

# Exhibit A

Michael P. Woods, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC :Master File No.  
REPAIR SYSTEM PRODUCTS :2:12-MD-02327  
LIABILITY LITIGATION :MDL No. 2327

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THIS DOCUMENT RELATES TO :JOSEPH R. GOODWIN  
THE CASES LISTED BELOW :U.S. DISTRICT JUDGE

Mullins, et al. v. 2:12-cv-02952  
Ethicon, Inc., et al.  
Sprout, et al. v. 2:12-cv-07924  
Ethicon, Inc., et al.  
Iquinto v. Ethicon, 2:12-cv-09765  
Inc., et al.  
Daniel, et al. v. 2:13-cv-02565  
Ethicon, Inc., et al.  
Dillon, et al. v. 2:13-cv-02919  
Ethicon, Inc., et al.  
Webb, et al. v. 2:13-cv-04517  
Ethicon, Inc., et al.  
Martinez v. Ethicon, 2:13-cv-04730  
Inc., et al.  
McIntyre, et al. v. 2:13-cv-07283  
Ethicon, Inc., et al.  
Oxley v. Ethicon, 2:13-cv-10150  
Inc., et al.  
Atkins, et al. v. 2:13-cv-11022  
Ethicon, Inc., et al.  
Garcia v. Ethicon, 2:13-cv-14355  
Inc., et al.  
Lowe v. Ethicon, 2:13-cv-14718  
Inc., et al.  
Dameron, et al. v. 2:13-cv-14799  
Ethicon, Inc., et al.  
Vanbuskir, et al. v. 2:13-cv-16183  
Ethicon, Inc., et al.

OCTOBER 5, 2015

MICHAEL P. WOODS, M.D.

GOLKOW TECHNOLOGIES, INC.

877.370.3377 ph | 917.591.5672 fax  
deps@golkow.com

## Michael P. Woods, M.D.

Page 2	Page 4
<p>1 CAPTION CONTINUED:</p> <p>2 Mullens, et al. v. 2:13-cv-16564</p> <p>3 Ethicon, Inc., et al.</p> <p>3 Shears, et al. v. 2:13-cv-17012</p> <p>3 Ethicon, Inc., et al.</p> <p>4 Javins, et al. v. 2:13-cv-18479</p> <p>4 Ethicon, Inc., et al.</p> <p>5 Barr, et al. v. 2:13-cv-22606</p> <p>5 Ethicon, Inc., et al.</p> <p>6 Lambert v. Ethicon, 2:13-cv-24393</p> <p>6 Inc., et al.</p> <p>7 Cook v. Ethicon, Inc., 2:13-cv-29260</p> <p>7 et al.</p> <p>8 Stevens v. Ethicon, 2:13-cv-29918</p> <p>8 Inc., et al.</p> <p>9 Harmon v. Ethicon, Inc., 2:13-cv-31818</p> <p>9 et al.</p> <p>10 Snodgrass v. Ethicon, 2:13-cv-31881</p> <p>10 Inc., et al.</p> <p>11 Miller v. Ethicon, Inc., 2:13-cv-32627</p> <p>11 et al.</p> <p>12 Matney, et al. v. 2:14-cv-09195</p> <p>12 Ethicon, Inc., et al.</p> <p>13 Jones, et al. v. 2:14-cv-09517</p> <p>13 Ethicon, Inc., et al.</p> <p>14 Humbert v. Ethicon, 2:14-cv-10640</p> <p>14 Inc., et al.</p> <p>15 Gillum, et al. v. 2:14-cv-12756</p> <p>15 Ethicon, Inc., et al.</p> <p>16 Whisner, et al. v. 2:14-cv-13023</p> <p>16 Ethicon, Inc., et al.</p> <p>17 Tomblin v. Ethicon, 2:14-cv-14664</p> <p>17 Inc., et al.</p> <p>18 Schepeling v. Ethicon, 2:14-cv-16061</p> <p>18 Inc., et al.</p> <p>19 Tyler, et al. v. 2:14-cv-19110</p> <p>19 Ethicon, Inc., et al.</p> <p>20 Kelly, et al. v. 2:14-cv-22079</p> <p>20 Ethicon, Inc., et al.</p> <p>21 Lindell v. Ethicon, 2:14-cv-24911</p> <p>21 Inc., et al.</p> <p>22 Cheshire, et al. v. 2:14-cv-24999</p> <p>22 Ethicon, Inc., et al.</p> <p>23 Burgoine, et al. v. 2:14-cv-28620</p> <p>23 Ethicon, Inc., et al.</p> <p>24 Bennett, et al. v. 2:14-cv-29624</p> <p>24 Ethicon, Inc., et al.</p> <p>25</p>	<p>1 A-P-P-E-A-R-A-N-C-E-S</p> <p>2</p> <p>3 FOR THE PLAINTIFFS:</p> <p>4 JEFFREY M. KUNTZ, ESQ.</p> <p>4 NATE JONES, ESQ.</p> <p>5 WAGSTAFF &amp; CARTMELL, LLP</p> <p>5 4740 Grand Avenue, Suite 300</p> <p>6 Kansas City, Missouri 64112</p> <p>6 (816) 701-1100 FAX (816) 531-2372</p> <p>7 E-mail: jkuntz@wcllp.com</p> <p>7 E-mail: njones@wcllp.com</p> <p>8</p> <p>9 FOR THE DEFENDANTS:</p> <p>10 NILS B. (BURT) SNELL, ESQ.</p> <p>10 BUTLER SNOW, LLP</p> <p>11 500 Office Center Drive</p> <p>11 Suite 400</p> <p>12 Fort Washington, Pennsylvania 19034</p> <p>12 (267) 513-1885 FAX (267) 513-1701</p> <p>13 E-mail: burt.snell@butlersnow.com</p> <p>14</p> <p>15 BUTLER SNOW, LLP</p> <p>15 PAUL S. ROSENBLATT, ESQ.</p> <p>15 1020 Highland Colony Parkway, Suite 1400</p> <p>16 Ridgeland, Mississippi 39157</p> <p>16 (601) 948-5711 FAX (601) 985-4500</p> <p>17 E-mail: paul.rosenblatt@butlersnow.com</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
Page 3	Page 5
<p>1 ---</p> <p>2 OCTOBER 5, 2015</p> <p>3 ---</p> <p>4</p> <p>5 Deposition of MICHAEL P. WOODS, M.D., called for</p> <p>6 examination, taken pursuant to the Federal Rules of</p> <p>7 Civil Procedure of the United States District Courts</p> <p>8 pertaining to the taking of depositions, taken before</p> <p>9 SONDRA W. PETERSEN, RMR, CRR, CSR, Notary Public for</p> <p>10 the State of Nebraska, at Getman &amp; Mills, LLP, 10250</p> <p>11 Regency Circle, Suite 105, Omaha, Nebraska, on</p> <p>12 October 5, 2015, at 9:40 a.m.</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 I-N-D-E-X</p> <p>2 PAGE</p> <p>3 CASE CAPTION ..... 1</p> <p>3 APPEARANCES ..... 4</p> <p>3 INDEX ..... 5</p> <p>4 TESTIMONY ..... 7</p> <p>4 ERRATA ..... 256</p> <p>5 REPORTER CERTIFICATE ..... 257</p> <p>6</p> <p>7 DIRECT EXAMINATION:</p> <p>7 By Mr. Kuntz ..... 7</p> <p>8 CROSS-EXAMINATION:</p> <p>8 By Mr. Snell ..... 187</p> <p>9 REDIRECT EXAMINATION:</p> <p>9 By Mr. Kuntz ..... 246</p> <p>10 RECROSS-EXAMINATION:</p> <p>10 By Mr. Snell ..... 253</p> <p>11</p> <p>12 EXHIBITS: MARKED</p> <p>13 1. DEPOSITION NOTICE ..... 48</p> <p>14 2. RULE 26 EXPERT REPORT - WOODS, MD ... 65</p> <p>15 3. POWERPOINT - PULL-OUT FORCE COMPARISON . 102</p> <p>16 4. CONSULTING AGREEMENT, 12/16/02 ..... 115</p> <p>17 5. CONSULTING AGREEMENT, 3/1/03 ..... 116</p> <p>18 6. CONSULTING AGREEMENT, 3/14/05 ..... 119</p> <p>19 7. CONSULTING AGREEMENT, 2/1/09 ..... 120</p> <p>20 8. CONSULTING AGREEMENT, 8/15/10 ..... 120</p> <p>21 9. CONSULTING AGREEMENT, 11/23/10 ..... 122</p> <p>22 10. HERNIA REPAIR SEQUELAE ..... 191</p> <p>23 11. THE COCHRANE COLLABORATION ..... 192</p> <p>24 12. SLING SURGERY FOR STRESS URINARY .... 196</p> <p>24 INCONTINENCE IN WOMEN AJOG ARTICLE</p> <p>25</p>

2 (Pages 2 to 5)

## Michael P. Woods, M.D.

<p>1           I-N-D-E-X 2            (Page 2)</p> <p>3   EXHIBITS:                   MARKED 4    13. APPENDIX A16, COMPLICATION RATES . . . 199 5    14. TENSION-FREE VAGINAL TAPE FOR THE . . . 201 6            TREATMENT OF URODYNAMIC STRESS INCONTINENCE 7            EAU ARTICLE 8    15. LONG-TERM FOLLOW-UP OF THE RETROPUBLIC . 223 9            TENSION-FREE VAGINAL TAPE PROCEDURE IUA 10           ARTICLE 11    16. TRANSOBTURATOR VS SINGLE-INCISION . . . 227 12           SUBURETHRAL MINI-SLINGS FOR TREATMENT OF 13           FEMALE STRESS URINARY INCONTINENCE ARTICLE 14    17. FIVE-YEAR RESULTS OF RANDOMIZED TRIAL . 236 15           ARTICLE 16 17 18 19 20 21 22 23 24 25</p>	<p>Page 6</p> <p>1            MR. SNELL: You can ask him the 2            question, but you can write them down. 3            MR. KUNTZ: Okay. 4            MR. SNELL: This is not a writing 5            deposition. This is an oral deposition. 6            Proceed. 7            MR. KUNTZ: Okay. 8    BY MR. KUNTZ: 9            Q. Doctor, tell me all of the complications 10           that exist with the TTVT Retropubic mechanical cut 11           mesh. 12           A. What I need to have refined to me: Is it 13           specific to TTVT or to all Retropubic suburethral or 14           colposuspensions? 15           Q. Okay. Let's start with all midurethral 16           slings. 17           A. Both autologous and mesh type? 18           Q. Let's start with autologous. 19           A. With autologous -- and I would like to 20           refer to the AUA -- I think that that -- excuse me 21           here. I'm going to look through it because I think 22           that gives a very nice comparison between the various 23           ones, so that way we can look at their referenced. 24           Okay. This is Guideline for Surgical 25           Management of Female Stress Urinary Incontinence 2009</p>
<p>Page 7</p> <p>1   MONDAY, OCTOBER 5, 2015, OMAHA, NEBRASKA 2           P R O C E E D I N G S 3           -oOo- 4           MICHAEL P. WOODS, M.D., 5           having been first duly sworn, was 6           examined and testified as follows: 7            DIRECT EXAMINATION 8    BY MR. KUNTZ: 9           Q. Please state your name for the record. 10           A. Michael Patrick Woods. 11           Q. And, Dr. Woods, I'm Jeff Kuntz. We met 12           earlier. You understand we're here for a deposition 13           that you've been named as an expert witness in the 14           Mullins v. Ethicon case? 15           A. Yes. 16           Q. Before we get started, I want to ask you if 17           you could write down on this piece of paper all of 18           the complications you know of that relate to the TTVT 19           Retropubic mechanical cut device. 20           A. Unique to -- 21           Q. No. Let me ask you this. 22           MR. SNELL: How about this. I'm going 23           to object. Why don't you write them down if you want 24           to ask him the question, Counsel. 25           MR. KUNTZ: I can ask him a question.</p>	<p>Page 9</p> <p>1           Update from the American Neurologic Association. 2           And we're going to go first to autologous; 3           is that correct? 4           Q. Sure. 5           A. And do you want -- 6           Q. Are they listed on -- what page are they 7           listed on? 8           A. This would be page -- doesn't have pages on 9           it. I will have to go -- and I'll give you the 10           appendix. 11           Q. Okay. 12           A. Appendix A11, Complication Rates 13           un-prolapsed, and I'm going to go first with 14           autologous fascia without bone anchors, and with -- 15           with that, 4 percent transfusion rate infection -- 16           Q. Doctor, I'm not asking for the rates. Just 17           give me the complications that you believe are 18           associated with it. 19           A. Okay. Infection, urinary tract infections, 20           bladder injury, bleeding acute, bowel injury, wound 21           infections, pain. 22           Now we'll go with without bone anchors. 23           Again, bleeding requiring transfusion--and also on 24           the other one bleeding requiring 25           transfusion--infection, urinary tract infection,</p>

Michael P. Woods, M.D.

Page 10	Page 12
<p>1 bladder injury, bleeding acute, urethral injury.  2 They also have an other: And abdominal and vaginal  3 wound infections.  4 Q. Okay. Any other complications you believe  5 are associated with that type of procedure?  6 A. There was a dyspareunia rate, but I'm not  7 able to locate that, so I will not speak to that at  8 this point.  9 Q. Do you believe dyspareunia is a  10 complication associated with a native tissue sling?  11 A. Yes.  12 Q. Okay. List all of the risks and  13 complications related to a synthetic mesh sling that  14 you believe exist.  15 A. Okay. What we have to do is also look at  16 synthetic at the bladder neck versus synthetic  17 midurethral sling. Also, you'd have to look at  18 different types of meshes, but in this AUA Appendix  19 A11 --  20 Q. Let's -- let me start, Doctor. Let's start  21 with the Ethicon TVT Retropubic synthetic mesh. What  22 are the complications associated with that device and  23 that procedure?  24 A. All of the above.  25 Q. All of them that you listed for native</p>	<p>1 damage to other organs that may or may not be  2 recognized at the time of surgery, including bowel,  3 bladder, ureters, great vessels, and the risk of mesh  4 erosion in the vagina of about 1 percent and into the  5 urethra or bladder at less than 1 percent.  6 Q. That's all of the warnings you would give  7 them?  8 A. Correct.  9 Q. Okay. Is there any other risks that you  10 know of that relate to the TVT Retropubic device made  11 by Ethicon?  12 A. There would be, also, the risk not only  13 with TVT Retropubic, but also other procedures, such  14 as autologous sling or Burch, which would include  15 nerve injury.  16 Q. Okay. Anything else?  17 A. Urinary retention.  18 Q. Anything else?  19 A. And voiding dysfunction.  20 Q. Anything else?  21 A. I cannot recall at this time.  22 Q. Okay. So every risk that you've listed out  23 here in the last minute, including the list for  24 native tissue repairs off Appendix 11, the risks  25 you've listed off Appendix A16, and then the list you</p>
<p style="text-align: center;">Page 11</p> <p>1 tissue sling?  2 A. I believe that, but I'm going to look on  3 the AUA.  4 Okay. So now what we'll do is we're going  5 to go, again following their appendix from the AUA --  6 Q. Which appendix?  7 A. This would be A16, no prolapse.  8 At the bladder neck, also includes bladder  9 injury and vaginal erosions. This is -- but this is  10 not TVT. That is just at the bladder neck. TVT is a  11 midurethral sling.  12 Q. So let me ask you this. Did the risks that  13 you just named for at the bladder neck apply to the  14 midurethral sling, as well?  15 A. Not nearly in the amount, so --  16 Q. And I'm not asking for percentage, Doc.  17 This is a really simple question. Do you put the TVT  18 Retropubic in still?  19 A. Yes.  20 Q. What do you tell your patients when they  21 come to the office? A patient asks --  22 A. Okay.  23 Q. -- "Tell me all of the risks associated  24 with this product," what would you tell them?  25 A. Bleeding, infection, scar tissue formation,</p>	<p style="text-align: center;">Page 13</p> <p>1 just named me are all of the risks that you know of  2 that exist related to the TVT Retropubic device made  3 by Ethicon?  4 MR. SNELL: Objection, compound.  5 Go ahead.  6 THE WITNESS: Also with any surgical  7 procedures, there's risk of death.  8 BY MR. KUNTZ:  9 Q. Okay. Anything else, as you sit here right  10 now? And you can add to it later if you want.  11 A. I may need to add to it later.  12 Q. Okay.  13 A. Again, when we talk about pain, I would  14 also include dyspareunia.  15 Q. Okay. Anything else?  16 A. Voiding dysfunction. I got -- I may add to  17 it later, but I can't recall off the top of my head  18 now.  19 Q. Do you know if Ethicon had knowledge of any  20 of those risks prior to the time it launched the TVT  21 device --  22 A. Yes.  23 Q. -- Retropubic?  24 Okay. Do you believe it had knowledge of  25 all of those risks at the time it launched the TVT</p>

Michael P. Woods, M.D.

Page 14	Page 16
<p>1 device?</p> <p>2 MR. SNELL: Objection, calls for</p> <p>3 speculation.</p> <p>4 BY MR. KUNTZ:</p> <p>5 Q. Well, let me ask you this. Have you</p> <p>6 reviewed any internal Ethicon documents or testimony</p> <p>7 of employees that talk about the risks they knew</p> <p>8 prior to the time the TVT was launched?</p> <p>9 A. When I talk about -- I was asked to look at</p> <p>10 levels of evidence in evaluating the safety and</p> <p>11 efficacy for --</p> <p>12 Q. I'm going to -- we can get into that and he</p> <p>13 can ask you. Just answer my question. Okay?</p> <p>14 Do you know, as you sit here right now,</p> <p>15 whether Ethicon had knowledge of all of these risks</p> <p>16 that you've listed out prior to the time the TVT was</p> <p>17 launched?</p> <p>18 A. Yes.</p> <p>19 Q. Okay.</p> <p>20 A. I have reviewed the internal documents;</p> <p>21 however, I've not allowed anecdotal,</p> <p>22 non-evidenced-based information to affect the safety</p> <p>23 and efficacy that I was asked to review.</p> <p>24 MR. KUNTZ: Okay. I'll move to strike</p> <p>25 after yes.</p>	<p>1 in forming and rendering your opinions that you're</p> <p>2 talking about today?</p> <p>3 A. No.</p> <p>4 Q. How many -- when I talk about TVT</p> <p>5 Retropubic, I'm talking about the Ethicon product.</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Do you understand that?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. How many TVT Retropubic devices have</p> <p>10 you placed in your career?</p> <p>11 A. Retropubic? A couple thousand.</p> <p>12 Q. Okay. 2,000?</p> <p>13 A. I would say plus or minus 500, yes.</p> <p>14 Q. Okay. Do you keep track of that number?</p> <p>15 A. I do not actively keep track of it anymore.</p> <p>16 Q. Okay. When did you stop keeping track of</p> <p>17 it?</p> <p>18 A. I'm still using Retropubic TVT, but I would</p> <p>19 say probably around 2007.</p> <p>20 Q. Okay. So you kept track of how many TVT</p> <p>21 Retropubic devices you used up until 2007, correct?</p> <p>22 A. 2007 or 2008.</p> <p>23 Q. Okay. Where is that list?</p> <p>24 A. I don't have it here.</p> <p>25 Q. Okay. But you do have it, right? We can</p>
<p style="text-align: center;">Page 15</p> <p>1 BY MR. KUNTZ:</p> <p>2 Q. You can -- and you're going to say that</p> <p>3 over and over again, I know that, and Burt can ask</p> <p>4 you those questions, but just answer my question for</p> <p>5 now. Okay?</p> <p>6 A. I'm aware of the internal documents.</p> <p>7 Q. Okay. So the answer -- your answer is,</p> <p>8 yes, Ethicon knew of all of the risks that you listed</p> <p>9 out for me prior to the launch of the TVT?</p> <p>10 MR. SNELL: Objection: Misstates,</p> <p>11 totally misstates. He said he's aware of the</p> <p>12 documents, but he did not consider that. You're</p> <p>13 misstating his testimony.</p> <p>14 BY MR. KUNTZ:</p> <p>15 Q. Okay. So you did not consider the Ethicon</p> <p>16 internal documents when forming your opinions that</p> <p>17 you're here to talk about today?</p> <p>18 A. Absolutely not.</p> <p>19 Q. Okay. So you don't rely on any Ethicon</p> <p>20 internal design documents in forming or giving your</p> <p>21 opinions today?</p> <p>22 A. I am looking at the evidence-based data</p> <p>23 that's available.</p> <p>24 Q. I think you just said, "Absolutely not."</p> <p>25 Did you rely on any Ethicon design internal documents</p>	<p style="text-align: center;">Page 17</p> <p>1 get a copy of it?</p> <p>2 A. I'm pulling that off of my memory.</p> <p>3 Q. Okay. So you do not have a formal list of</p> <p>4 how many --</p> <p>5 A. No.</p> <p>6 Q. -- TVT Retropubic devices you've kept</p> <p>7 (sic), right?</p> <p>8 A. No.</p> <p>9 Q. Okay. And up to 2007, how many devices --</p> <p>10 how many TVT Retropubic devices did you place?</p> <p>11 A. I probably placed about 12 or 13 a year.</p> <p>12 Q. Okay. Is that from the first time you used</p> <p>13 it in 1999, I believe, to present date?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. So -- and I apologize. I'm</p> <p>16 confused. So is 2,000 the total amount of just TVT</p> <p>17 slings in general you have placed, including TVT</p> <p>18 Secur, TVT-O?</p> <p>19 A. No.</p> <p>20 Q. Okay. So you -- it's your testimony that</p> <p>21 you've placed 2,000 TVT Retropubic devices?</p> <p>22 A. Plus or minus about 500, yes.</p> <p>23 Q. Okay. But you don't have any type of</p> <p>24 formal list documenting that?</p> <p>25 A. No.</p>

5 (Pages 14 to 17)

Michael P. Woods, M.D.

<p style="text-align: center;">Page 18</p> <p>1 Q. Do you perform your Retropubic TTV 2 placement under general or local anesthesia?</p> <p>3 A. I go to multiple different hospitals and so 4 I have placed it under both general, regional, and 5 local anesthetic.</p> <p>6 Q. What's the majority of your placements done 7 under?</p> <p>8 A. Now it is sedation and local.</p> <p>9 Q. What's the pore size of the Prolene mesh in 10 the TTV Retropubic device?</p> <p>11 A. It's an Amid classification Type I 12 macroporous mesh that's greater than 75 microns.</p> <p>13 Q. Why does Ethicon call the Prolene mesh the 14 old construction mesh?</p> <p>15 MR. SNELL: Objection: Form, 16 foundation.</p> <p>17 THE WITNESS: I'm not aware they do.</p> <p>18 BY MR. KUNTZ:</p> <p>19 Q. Okay. So as you sit here today, you didn't 20 know that Ethicon calls the Prolene mesh using the 21 TTV device the old construction mesh?</p> <p>22 MR. SNELL: Same objection.</p> <p>23 THE WITNESS: I am aware --</p> <p>24 BY MR. KUNTZ:</p> <p>25 Q. Do you know that or not?</p>	<p style="text-align: center;">Page 20</p> <p>1 MR. SNELL: Objection, form. Are you 2 still talking TTV, because you just made a broad --</p> <p>3 MR. KUNTZ: Yes.</p> <p>4 MR. SNELL: You said "devices." You 5 didn't say "TTV."</p> <p>6 BY MR. KUNTZ:</p> <p>7 Q. I'll tell you if I'm talking about 8 something other than the TTV, like I said 10 minutes 9 ago.</p> <p>10 MR. SNELL: I will note that for the 11 record. I just want a clear record, that's all.</p> <p>12 THE WITNESS: No, I do not.</p> <p>13 BY MR. KUNTZ:</p> <p>14 Q. Okay. So you don't have any idea how many 15 laser cut TTV Retropubic devices you've placed as we 16 sit here today?</p> <p>17 A. No, I do not.</p> <p>18 Q. Okay. You don't keep track of the 19 difference between mechanical cut mesh TTV 20 Retropubics you place and laser cut?</p> <p>21 A. No.</p> <p>22 MR. SNELL: Hold on. Objection: 23 Form, misstates. He already told you there's no 24 difference in his opinion.</p> <p>25 THE WITNESS: Would you please repeat</p>
<p style="text-align: center;">Page 19</p> <p>1 MR. SNELL: He's about to answer your 2 question. Don't interrupt him.</p> <p>3 THE WITNESS: I am aware that it is a 4 mesh that has been utilized and studied extensively 5 over the years, so the original studies looking at 6 the Retropubic TTV are one of the older meshes, yes.</p> <p>7 BY MR. KUNTZ:</p> <p>8 Q. Okay. Have you ever heard it called the 9 old construction mesh?</p> <p>10 A. No.</p> <p>11 Q. How many TTV Retropubic devices with laser 12 cut mesh have you placed?</p> <p>13 A. The laser cut came out I believe in 2007. 14 And this is for Retropubic or all my TTV --</p> <p>15 Q. Retropubics.</p> <p>16 A. I really don't know. It depends on the 17 hospital. When I open the package, it doesn't really 18 matter whether it's laser cut or mechanically cut. I 19 place it the same way.</p> <p>20 Q. How do you know the difference?</p> <p>21 A. I can actually see it because it's right in 22 front of my eyes.</p> <p>23 Q. Okay. Do you have any idea how many laser 24 cut Retropubic devices you've placed?</p> <p>25 A. No.</p>	<p style="text-align: center;">Page 21</p> <p>1 that question.</p> <p>2 BY MR. KUNTZ:</p> <p>3 Q. Did you just testify that you can tell the 4 difference between laser cut and mechanical cut mesh 5 by looking at it?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Have you ever kept track or kept a 8 chart of the differences in what you've placed, be it 9 mechanical cut or laser cut?</p> <p>10 MR. SNELL: Form.</p> <p>11 THE WITNESS: No, because it --</p> <p>12 BY MR. KUNTZ:</p> <p>13 Q. Okay. And so as we sit here --</p> <p>14 MR. SNELL: Hold on. He's not done 15 answering. He's not done answering.</p> <p>16 You can finish.</p> <p>17 THE WITNESS: No. I can tell the 18 difference when I see it. I do not track it and I do 19 not feel it impacts my success rates --</p> <p>20 BY MR. KUNTZ:</p> <p>21 Q. Okay.</p> <p>22 A. -- or complication rates.</p> <p>23 Q. Okay. Have you ever tracked your 24 complication rates as they may relate to laser cut mesh or mechanical cut mesh?</p>

6 (Pages 18 to 21)

Michael P. Woods, M.D.

Page 22	Page 24
<p>1 A. No.</p> <p>2 Q. What hospitals have you implanted mesh at</p> <p>3 since 2007?</p> <p>4 A. Jennie Edmundson Hospital, Council Bluffs.</p> <p>5 Q. In?</p> <p>6 A. Council Bluffs, Iowa.</p> <p>7 Q. Okay. And do you -- did you dictate to the</p> <p>8 hospital what mesh they should order, laser cut or</p> <p>9 mechanical cut?</p> <p>10 A. No.</p> <p>11 Q. Okay. Did you dictate to the hospital what</p> <p>12 product they should order?</p> <p>13 A. I -- at all of my hospitals at that time</p> <p>14 were all using the Ethicon product.</p> <p>15 Q. Okay. Did they use laser cut mesh at that</p> <p>16 hospital in the TVT Retropubic?</p> <p>17 A. I do not recall.</p> <p>18 Q. Okay. Who is in charge of purchasing at</p> <p>19 that hospital, do you know?</p> <p>20 A. It would be the purchasing department.</p> <p>21 Q. Okay. And they were in charge of</p> <p>22 purchasing all of the Ethicon product that you would</p> <p>23 use in surgery at that hospital?</p> <p>24 A. And the other surgeons, yes.</p> <p>25 Q. What other hospitals have you placed</p>	<p>1 Q. Okay. How did you first learn about it?</p> <p>2 A. I'm not sure.</p> <p>3 Q. On Page 16 of your report, you state</p> <p>4 that -- go ahead and turn there.</p> <p>5 You see on Page 16, that laser cut mesh was</p> <p>6 a marketing effort. Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. What do you mean by that?</p> <p>9 A. I attended the TVT summits and we were</p> <p>10 asked, as a group, what did we think about this.</p> <p>11 And you had physicians that were present</p> <p>12 that said, "I only want to use mechanical cut." I</p> <p>13 had physicians that said, "It really doesn't matter."</p> <p>14 And there were other physicians who were willing to</p> <p>15 try the laser cut. And that's, I believe, how I</p> <p>16 learned about it.</p> <p>17 Q. Okay. What do you mean by marketing</p> <p>18 effort, though; what does that mean to you?</p> <p>19 A. They asked -- they asked, "Do you feel that</p> <p>20 physicians would want to see this different?"</p> <p>21 Q. Okay. So was it an effort to sell more</p> <p>22 slings?</p> <p>23 A. No, I don't -- at that, they were just</p> <p>24 asking our opinion. I'm sure there's a marketing</p> <p>25 component, but they just asked our opinion.</p>
<p style="text-align: center;">Page 23</p> <p>1 Ethicon products at since 2007?</p> <p>2 A. University of Nebraska Medical Center;</p> <p>3 Denison Hospital -- or Crawford County Memorial</p> <p>4 Hospital in Denison, Iowa; Manning Regional</p> <p>5 HealthCare Center in Manning, Iowa; Audubon Community</p> <p>6 Hospital; Shenandoah Community Hospital.</p> <p>7 Q. And did you dictate to any of those --</p> <p>8 A. And Myrtle Memorial Hospital in Harlan,</p> <p>9 M-Y-R-T-U-E.</p> <p>10 Q. Did you tell any of those hospitals which</p> <p>11 product to purchase?</p> <p>12 MR. SNELL: Form.</p> <p>13 THE WITNESS: I requested the Ethicon</p> <p>14 products.</p> <p>15 BY MR. KUNTZ:</p> <p>16 Q. Okay. Did you request laser cut or</p> <p>17 mechanical cut, specifically?</p> <p>18 A. No.</p> <p>19 Q. Again, you never kept track while you were</p> <p>20 at those hospitals which product you were using, be</p> <p>21 it laser cut or mechanical cut?</p> <p>22 A. No.</p> <p>23 Q. When was laser cut mesh first sold?</p> <p>24 A. In the United States--I'm not positive on</p> <p>25 this--I believe it was around 2007.</p>	<p style="text-align: center;">Page 25</p> <p>1 Q. In any of those TVT summits where they</p> <p>2 introduced laser cut mesh, did you ever talk to any</p> <p>3 physicians there that thought the two meshes were not</p> <p>4 the same?</p> <p>5 MR. SNELL: Objection, lacks</p> <p>6 foundation.</p> <p>7 THE WITNESS: If I were -- physicians</p> <p>8 always have their opinions, but what I -- what I do</p> <p>9 is I take -- I look at opinions, but what I -- when</p> <p>10 I'm looking at implanting something into a patient of</p> <p>11 mine, and in order to properly counsel them and</p> <p>12 provide the best care, I have to look at what the</p> <p>13 best evidence is. So I respect physicians' opinions,</p> <p>14 however that is very low on what determines how I do</p> <p>15 things.</p> <p>16 BY MR. KUNTZ:</p> <p>17 Q. Okay. And I'm going to ask you to answer</p> <p>18 my question. Were you -- when you were at any of</p> <p>19 those summits, did you ever talk to any physicians</p> <p>20 that felt that the laser cut mesh was different than</p> <p>21 the mechanical cut mesh?</p> <p>22 A. I -- I'm sure I did. I just don't recall</p> <p>23 specific physicians at all.</p> <p>24 Q. Have you ever reviewed any internal Ethicon</p> <p>25 documents that discuss there being a difference</p>

Michael P. Woods, M.D.

Page 26	Page 28
<p>1 between the laser cut mesh and a mechanical cut mesh?</p> <p>2 A. I believe that there were documents that</p> <p>3 did discuss a difference on it.</p> <p>4 Q. Okay. And what difference was that?</p> <p>5 A. That it was -- I have to look at the</p> <p>6 internal documents. Do we have the internal</p> <p>7 documents in --</p> <p>8 Q. They're all right there, the ones you've</p> <p>9 reviewed.</p> <p>10 A. Okay.</p> <p>11 MR. SNELL: We have the thumb drive,</p> <p>12 too, if we need to get that out for you.</p> <p>13 THE WITNESS: I apologize here. I</p> <p>14 must admit, there was just a huge amount of material</p> <p>15 to go through.</p> <p>16 I don't see the internal documents in here.</p> <p>17 BY MR. KUNTZ:</p> <p>18 Q. Okay. We can go --</p> <p>19 MR. SNELL: Do you want to look at it</p> <p>20 at a break?</p> <p>21 MR. KUNTZ: Yeah.</p> <p>22 MR. SNELL: He's got a thumb drive,</p> <p>23 so...</p> <p>24 MR. KUNTZ: Yeah, we'll look at it at</p> <p>25 the break.</p>	<p>1 A. I have not --</p> <p>2 MR. SNELL: Form.</p> <p>3 Go ahead.</p> <p>4 THE WITNESS: I -- in my own</p> <p>5 experience, I have not seen any difference.</p> <p>6 BY MR. KUNTZ:</p> <p>7 Q. What other products have you used for the</p> <p>8 treatment of stress urinary incontinence?</p> <p>9 A. I have used TVT-O, TTV Abbrevio, TTV Secur,</p> <p>10 MiniArc, and Altis. Also, I have used peri-urethral</p> <p>11 bulking agents.</p> <p>12 Q. What of the last one you said after</p> <p>13 MiniArc?</p> <p>14 A. Altis.</p> <p>15 Q. Who makes that?</p> <p>16 A. Coloplast. I actually was in their FDA</p> <p>17 study.</p> <p>18 Q. Okay. You -- I think you said in your</p> <p>19 report you started using midurethral slings in 1999</p> <p>20 after monitoring the literature?</p> <p>21 A. Yes.</p> <p>22 Q. What literature?</p> <p>23 A. This would have been Ulmsten's studies,</p> <p>24 also the studies out of Sweden where they looked at</p> <p>25 the multi-center studies, and, also, there was</p>
Page 27	Page 29
<p>1 MR. SNELL: What's that? Oh, that's</p> <p>2 not...</p> <p>3 BY MR. KUNTZ:</p> <p>4 Q. So you believe you've reviewed some</p> <p>5 internal Ethicon documents that talk about there</p> <p>6 being a difference between a mechanical cut and laser</p> <p>7 cut mesh?</p> <p>8 A. From their benchtop. They were not surgeon</p> <p>9 specific, no.</p> <p>10 Q. Have you ever reviewed any Ethicon internal</p> <p>11 documents that suggest that the Nilsson/Ulmsten</p> <p>12 long-term data should not be used to support laser</p> <p>13 cut mesh?</p> <p>14 A. In that long-term data, because it was the</p> <p>15 old mesh, they can't use a laser cut in that.</p> <p>16 Q. Okay. So you don't believe that the</p> <p>17 long-term data can support the laser cut mesh; is</p> <p>18 that what you said?</p> <p>19 A. I believe that the longest-term studies,</p> <p>20 because it was not available, cannot.</p> <p>21 Q. Okay. If I'm understanding you right,</p> <p>22 you're saying there's some doctors that might think</p> <p>23 it's different, but, in your opinion, it is not --</p> <p>24 there's no difference between the laser cut and</p> <p>25 mechanical cut mesh?</p>	<p>1 starting to be other data coming out of Europe that</p> <p>2 replicated that.</p> <p>3 Q. Okay. So you believe there were studies</p> <p>4 out of the Scandinavian group and then the Swedish</p> <p>5 group?</p> <p>6 A. And I -- there was also -- in going to</p> <p>7 different meetings and talking with surgeons, and</p> <p>8 everything, where it wasn't in the U.S. yet, I was</p> <p>9 very interested because I have done slings for --</p> <p>10 ever since my second year of residency; and I was</p> <p>11 very excited to see the differences that could be</p> <p>12 happening.</p> <p>13 Q. Do you agree that your knowledge regarding</p> <p>14 Prolene use in the hernia repairs was relevant in</p> <p>15 your original decision to use it in the pelvic floor?</p> <p>16 A. No.</p> <p>17 Q. Did you review the hernia literature on</p> <p>18 Prolene prior to using the Prolene sling?</p> <p>19 A. I spoke with my general surgeon colleagues,</p> <p>20 and this was early on, where they felt that the</p> <p>21 polypropylene mesh, the macroporous mesh looked like</p> <p>22 it was better.</p> <p>23 Q. Okay. So you relied on your general</p> <p>24 surgery colleagues who were using Prolene as part of</p> <p>25 your decision process in looking at the TTV sling</p>

8 (Pages 26 to 29)

## Michael P. Woods, M.D.

Page 30	Page 32
<p>1 made of Prolene?</p> <p>2 A. Yes.</p> <p>3 Q. Who were the authors of the Swedish papers</p> <p>4 that you first looked at in 1999?</p> <p>5 A. Petros and Ulmsten were some of the</p> <p>6 authors. I'm terrible with names, so as we go</p> <p>7 through, I may have to look at some -- you know, some</p> <p>8 of those on that.</p> <p>9 But one of the things that I was interested</p> <p>10 in was, actually, Amid classification. I had a mesh</p> <p>11 that I used intra-abdominally that migrated, and it</p> <p>12 really challenged me. And this was a Type III mesh.</p> <p>13 And when we were first doing slings and when I was in</p> <p>14 residency, we were looking at different ways, besides</p> <p>15 autologous, and we just did not have good results.</p> <p>16 Q. Do you still use the Amid classification</p> <p>17 today?</p> <p>18 A. Yes, I do.</p> <p>19 Q. Have you read -- reviewed any literature</p> <p>20 that -- recent literature that discusses the</p> <p>21 relevancy of the Amid classification?</p> <p>22 A. I did in selecting -- when TVT came out,</p> <p>23 was look at the Amid classification with macroporous</p> <p>24 mesh. I had a special interest because I had used</p> <p>25 Mersilene mesh, I had used Gore-Tex, I had used</p>	<p>1 believed it was within the standard of care to do so,</p> <p>2 correct?</p> <p>3 A. I believe that -- at that time, we were</p> <p>4 trying to figure out -- if I would do things</p> <p>5 differently today, I would absolutely be doing it an</p> <p>6 IRB-approved setting, and I wasn't at that level.</p> <p>7 Q. Okay. My question was: When you were</p> <p>8 placing Gore-Tex, did you believe it was within the</p> <p>9 standard of care to place it?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. Today, do you think it would be</p> <p>12 below the standard of care to place Gore-Tex --</p> <p>13 A. Absolutely, for a midurethral sling.</p> <p>14 Q. Okay. Same question with regard to</p> <p>15 Mersilene?</p> <p>16 A. No. The erosion rate is very high.</p> <p>17 Q. Okay. So when you were using it, you agree</p> <p>18 Mersilene was within the standard of care, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you'd agree today that it would be</p> <p>21 outside the standard of care to use Mersilene for</p> <p>22 a --</p> <p>23 A. Yes.</p> <p>24 Q. -- midurethral sling?</p> <p>25 A. Yes.</p>
<p style="text-align: center;">Page 31</p> <p>1 bovine dura mater. I had had numerous poor results.</p> <p>2 Q. Right.</p> <p>3 A. And the Amid classification made sense from</p> <p>4 a macroporous aspect, and so I was looking at that</p> <p>5 for part of my literature.</p> <p>6 Q. And that's not what I asked.</p> <p>7 Have you reviewed any recent literature</p> <p>8 discussing the relevancy of the Amid classification?</p> <p>9 A. No, I have not.</p> <p>10 Q. Okay. Have you reviewed any presentations</p> <p>11 from any of the incontinence groups regarding the</p> <p>12 relevancy of the Amid classification?</p> <p>13 A. No, I have not.</p> <p>14 Q. Okay. Have you reviewed any internal</p> <p>15 Ethicon documents that discuss their concerns about</p> <p>16 the Amid classification?</p> <p>17 A. No.</p> <p>18 Q. You said you used -- in what way did you</p> <p>19 use Gore-Tex previously?</p> <p>20 A. I had used it suburethrally, in suburethral</p> <p>21 slings. Also, I used it -- there was some initial</p> <p>22 data on adhesion prevention; and I had also seen some</p> <p>23 of the literature in hernia, but it just did not</p> <p>24 work.</p> <p>25 Q. Okay. When you were using Gore-Tex, you</p>	<p style="text-align: center;">Page 33</p> <p>1 Q. Okay. Did you ever use the Proregion (ph)</p> <p>2 device?</p> <p>3 A. No.</p> <p>4 Q. Do you know how much Ulmsten has been paid</p> <p>5 by Ethicon?</p> <p>6 MR. SNELL: Objection, form.</p> <p>7 Go ahead.</p> <p>8 THE WITNESS: Ulmsten is dead and --</p> <p>9 BY MR. KUNTZ:</p> <p>10 Q. Do you know how much Ulmsten's estate has</p> <p>11 been paid by Ethicon?</p> <p>12 A. No, I do not.</p> <p>13 Q. Okay. Do you know how much Ulmsten was</p> <p>14 paid by Ethicon when he was alive?</p> <p>15 A. I saw something of \$400,000 if the study</p> <p>16 could be replicated.</p> <p>17 Q. Do you know in total how much Ulmsten was</p> <p>18 paid by Ethicon prior to his death?</p> <p>19 A. No, I do not.</p> <p>20 Q. Do you know how much his estate has been</p> <p>21 paid since his death?</p> <p>22 A. No.</p> <p>23 Q. Okay. Do you know how much Dr. Nilsson has</p> <p>24 been paid by Ethicon?</p> <p>25 A. No, I do not.</p>

Michael P. Woods, M.D.

<p style="text-align: right;">Page 34</p> <p>1 Q. Okay. You talked about migration of the 2 mesh with Mersilene, I believe. 3 A. No, that was with the Gore-Tex. 4 Q. I'm sorry, with the Gore-Tex. 5 A. Yes. 6 Q. What are the complications from the 7 migration of the Gore-Tex mesh? 8 A. In that case, there was no complications. 9 It was just a woman had passed it per rectum three 10 months after surgery. 11 Q. Okay. That's the only complications you 12 saw from the migration of the Gore-Tex mesh? 13 A. That I have personally seen, yes. 14 Q. Okay. What other complications were you 15 aware of from the migration of the Gore-Tex mesh? 16 A. I would say it was my personal experience 17 in that one case. 18 Q. Okay. Have you ever reviewed any documents 19 that suggest that the TVT mesh can migrate? 20 A. I am unaware of the TVT Retropubic sling 21 mesh migrating. 22 Q. Okay. So you've never seen any documents 23 or any study that suggests that the TVT mesh can 24 migrate? 25 A. I have not seen any Level 1 studies,</p>	<p style="text-align: right;">Page 36</p> <p>1 talking about the original one or the Exact? 2 A. I've used -- I use both, depending on the 3 hospital. 4 Q. Which hospital do you use the, I'll call 5 it, classic TVT Retropubic? 6 A. It varies. Again, that is with purchasing, 7 so whatever they hand me, I'm very comfortable using. 8 Q. Okay. Do you know which hospitals you're 9 currently at use the classic as compared to the 10 Exact? 11 A. No, I really can't say. It's just whatever 12 they hand me when I do it. I really -- I really 13 don't pay attention to which one it is. 14 Q. So you have no way to track which product 15 you use more often currently? 16 A. No. 17 Q. What hospitals are you currently doing 18 surgery at? 19 A. So it would be at the present time Myrtle 20 Memorial Hospital, it would be Audubon Community 21 Hospital, Manning Regional HealthCare, Shenandoah 22 Community Health Center or Shenandoah Medical Center. 23 Q. And is purchasing at those hospitals 24 responsible for what products are ordered for you to 25 use in surgery?</p>
<p style="text-align: right;">Page 35</p> <p>1 systemic reviews, or meta-analysis that show that it 2 migrates. 3 Q. Okay. So you have not seen any studies, 4 correct? 5 A. I have not seen any high-level studies. 6 Q. Okay. Have you ever seen any internal 7 documents that suggest that it can migrate? 8 A. No, I do not recall. 9 Q. Do you know if Dr. Petros ever consulted or 10 was ever paid by Ethicon? 11 A. Yes, Dr. Petros worked with Dr. Ulmsten. 12 Q. Do you know how much Dr. Petros was paid by 13 Ethicon? 14 A. No, I do not. 15 Q. What current products are you using for the 16 treatment of stress urinary incontinence? 17 A. I'm using Retropubic TVT, I'm using TVT 18 Abbrevo, I'm using TVT-O. I have been using some of 19 the MiniArcs just recently after the -- it showed 20 clinical effectiveness similar to the Monarc. I use 21 peri-urethral bulking agents, and plus I use the 22 stage -- first stage which would be the pelvic floor 23 and -- pelvic floor exercises, timed voiding 24 techniques, behavior modification. 25 Q. When you say TVT Retropubic, are you</p>	<p style="text-align: right;">Page 37</p> <p>1 A. I would suspect so. 2 Q. Okay. Do you know who the purchasing 3 agents are at each one of those hospitals? 4 A. No. No, I do not. 5 Q. Do they have a purchasing department? 6 A. Some of these are small hospitals. I don't 7 even know if they have a purchasing department. 8 Q. Okay. Do you talk to anybody about 9 purchasing there? 10 A. No. I just schedule my surgery. 11 Q. So you have no idea at those hospitals 12 who's responsible for putting the product on the 13 shelf? 14 A. Pretty much, yes. 15 Q. Okay. No idea? 16 A. Honestly, no idea. 17 Q. Okay. Do you know who the sales rep -- 18 Ethicon sales rep is for those hospitals? 19 A. I'm not even sure who the Ethicon sales rep 20 is. 21 Q. Who is your Ethicon sales rep? 22 A. I'm unsure. They've had a lot of turn- -- 23 I don't know, I haven't seen them in quite a while. 24 I haven't had an Ethicon rep in quite a while. 25 Q. So how many Ethicon products do you put in</p>

Michael P. Woods, M.D.

Page 38	Page 40
<p>1 a week?</p> <p>2 A. I would say, in a week, it could be</p> <p>3 anywhere from three to seven.</p> <p>4 Q. Okay. And you have no idea who the Ethicon</p> <p>5 sales rep is for your area?</p> <p>6 A. No, I don't.</p> <p>7 Q. Okay. And you have no idea how those three</p> <p>8 to seven products get on the shelf?</p> <p>9 A. They know when I schedule. That's --</p> <p>10 that's all I care about is that the product is there</p> <p>11 when I get started.</p> <p>12 Q. You agree that the TVT Exact only uses</p> <p>13 laser cut mesh?</p> <p>14 A. Yes.</p> <p>15 Q. Do you agree it's not sold with mechanical</p> <p>16 cut mesh?</p> <p>17 A. I do not believe -- I'm not absolutely</p> <p>18 certain on that, but I do not believe it's</p> <p>19 mechanically cut.</p> <p>20 Q. Okay. So as you sit here today, you don't</p> <p>21 know whether the TVT Exact is sold in mechanical cut</p> <p>22 mesh or not?</p> <p>23 A. I do not recall seeing the mechanical cut,</p> <p>24 no.</p> <p>25 Q. So is the answer -- do you know or do you</p>	<p>1 MR. SNELL: Form.</p> <p>2 THE WITNESS: I have not seen it in a</p> <p>3 mechanical cut.</p> <p>4 BY MR. KUNTZ:</p> <p>5 Q. You still didn't answer my question.</p> <p>6 MR. SNELL: Yeah, he did. He just</p> <p>7 told you he hasn't seen a TVT Exact in mechanical</p> <p>8 cut.</p> <p>9 MR. KUNTZ: That's a different</p> <p>10 question whether he seen it or not.</p> <p>11 BY MR. KUNTZ:</p> <p>12 Q. Do you know, as you sit here today, whether</p> <p>13 the TVT Exact is sold in mechanical cut mesh or not?</p> <p>14 A. I do not believe, but I cannot say with</p> <p>15 100 percent certainty.</p> <p>16 Q. Thank you.</p> <p>17 Doctor, have you ever said that the TVT</p> <p>18 Exact is an improvement over the TVT Retropubic</p> <p>19 classic?</p> <p>20 A. No.</p> <p>21 Q. Okay. You've never uttered those words?</p> <p>22 A. When I placed the first TVT Exact, I was</p> <p>23 very surprised how easily it passed through the</p> <p>24 tissue. I don't know if I said it's better or not to</p> <p>25 be honest with you.</p>
<p style="text-align: center;">Page 39</p> <p>1 not know?</p> <p>2 MR. SNELL: Objection, form. He just</p> <p>3 told you. He's already answered this twice.</p> <p>4 MR. KUNTZ: He said he didn't know,</p> <p>5 Burt.</p> <p>6 MR. SNELL: No, he said --</p> <p>7 MR. KUNTZ: I'm trying to find --</p> <p>8 look --</p> <p>9 MR. SNELL: Go ahead, answer him a</p> <p>10 third time. Tell him the same thing.</p> <p>11 BY MR. KUNTZ:</p> <p>12 Q. Do you know or not whether the TVT Exact is</p> <p>13 sold in mechanical cut mesh?</p> <p>14 A. When I have it in my hand, I can tell. I</p> <p>15 don't pay attention if it's mechanical cut or not in</p> <p>16 placing the device.</p> <p>17 Q. So the answer is you don't know?</p> <p>18 MR. SNELL: Objection. He just told</p> <p>19 you he does know.</p> <p>20 THE WITNESS: When I have it in my</p> <p>21 hand --</p> <p>22 BY MR. KUNTZ:</p> <p>23 Q. This is really simple, Doctor. Do you know</p> <p>24 whether the TVT Exact is sold in mechanical cut mesh</p> <p>25 or not? Yes or no question.</p>	<p style="text-align: center;">Page 41</p> <p>1 Q. When did you place your first TVT Exact?</p> <p>2 A. I don't recall the exact date. I know I</p> <p>3 was one of the first people in the area.</p> <p>4 Q. Okay. And you've never said that the</p> <p>5 device is a definite improvement over the TVT</p> <p>6 classic?</p> <p>7 MR. SNELL: Form.</p> <p>8 THE WITNESS: If it would be the ease</p> <p>9 of passage, I might have said that because it</p> <p>10 surprised me in how quickly it passed through the</p> <p>11 tissues.</p> <p>12 BY MR. KUNTZ:</p> <p>13 Q. Okay. Have you ever said that the TVT-S</p> <p>14 was better than the TVT Retropubic?</p> <p>15 MR. SNELL: Form. TVT Secur? I</p> <p>16 didn't hear your question. I'm sorry.</p> <p>17 BY MR. KUNTZ:</p> <p>18 Q. Have you ever said that the TVT -- you know</p> <p>19 what TVT-S is, don't you, Doctor?</p> <p>20 A. TVT Secur, yes.</p> <p>21 Q. Okay. Have you ever said that the TVT</p> <p>22 Secur was better than the TVT Retropubic?</p> <p>23 A. I felt that it was equal.</p> <p>24 And could I qualify that a little bit more?</p> <p>25 Q. Sure.</p>

Michael P. Woods, M.D.

Page 42	Page 44
<p>1                   MR. SNELL: You can give your answers.    2 Tell him your answer -- honest answers.    3                   THE WITNESS: In many cases, there is    4 still times when I've felt that the Retropubic was a    5 better choice, depending on the clinical situation.    6 BY MR. KUNTZ:    7                   Q. Do you know whether the MiniArc is    8 mechanically cut or laser cut?    9                   A. Honestly, I -- I don't know.    10                  Q. Okay. Do you know the weight of the    11 MiniArc?    12                  A. Not off the top of my head.    13                  Q. Do you know the pore size of the MiniArc?    14                  A. I know it's a Amid classification Type I    15 macroporous mesh.    16                  Q. When did you first start using MiniArc?    17                  A. Just recently. I was interested in a    18 single-incision sling and the company had approached    19 me. I went off for training. And I believe I have    20 implanted probably four or five.    21                  Q. You no longer use Ethicon single-incision    22 sling because it's off the market, correct?    23                  A. That's correct.    24                  Q. Okay. Do you know why it was taken off the    25 market?</p>	<p>1                   A. They quit manufacturing them, correct.    2                  Q. Okay. Were they all subject to 522 orders?    3                  A. Yes.    4                  Q. Okay. Did you review any of the 522 orders    5 for any of those devices?    6                  A. For Ethicon's products, no.    7                  Q. Okay. Did you review any internal    8 documents from Ethicon, including their responses to    9 the 522 orders?    10                 A. No, I do not recall.    11                 Q. So four different Ethicon products that you    12 once promoted and used are now off the market,    13 correct?    14                 MR. SNELL: Objection, form.    15                 THE WITNESS: They quit manufacturing    16 them.    17 BY MR. KUNTZ:    18                 Q. Okay. And do you know why they quit    19 manufacturing them?    20                 A. That was a corporate decision. I am not    21 privy to that.    22                 Q. Okay. Do you believe it's still within the    23 standard of care to place a POP kit?    24                 A. I believe, in the appropriate situations,    25 yes.</p>
<p style="text-align: center;">Page 43</p> <p>1                  A. I believe that with the 522 studies that    2 they felt that they would not proceed with its    3 manufacture, but I don't know the exact reason they    4 pulled it off.    5                  Q. Do you know what a 522 order is?    6                  A. The 522 order was that it is under    7 increased scrutiny with the FDA and it allows for    8 further evaluation. They have to do -- look at    9 almost a PMA submission.    10                 Q. Okay. Have you ever reviewed the 522    11 orders in this case -- or strike that.    12                 Have you ever reviewed the 522 orders for    13 the TVT Secur?    14                 A. They were the same for all mini slings. I    15 may have reviewed it at some time. I don't recall    16 off the top of my head.    17                 Q. Okay. And you've used the Prolift and the    18 Prosimax, as well, correct?    19                 A. Yes, I have.    20                 Q. And Prolift+M, correct?    21                 A. Yes.    22                 Q. Okay. And none of those products are no    23 longer on -- strike that.    24                 All of those products are now off the    25 market, correct?</p>	<p style="text-align: center;">Page 45</p> <p>1                 Q. Okay. And what is the appropriate    2 situation?    3                 A. I believe that it's between the patient and    4 the physician, and that the registries, especially    5 for the studies, need to be done in order to be in    6 compliance with the 522, and it should not be used as    7 the primary repair --    8                 Q. Okay.    9                 A. -- in patients, more of a recurrence.    10                 Q. Okay. So you agree it's below the standard    11 of care to use a POP product for a primary repair?    12                 MR. SNELL: Objection: Form,    13 missates.    14 BY MR. KUNTZ:    15                 Q. Let me ask you. Do you -- let me restate.    16 Do you believe it's below the standard of care to use    17 a POP product for primary repair?    18                 MR. SNELL: No, hold on. Hold on.    19 Objection: Overbroad, missates. If you want to    20 hear why I'm objecting --    21                 MR. KUNTZ: I don't care. I don't    22 care. You can have the objection for the record.    23 That's fine.    24                 MR. SNELL: You say POP product, then.    25</p>

Michael P. Woods, M.D.

<p style="text-align: center;">Page 46</p> <p>1 BY MR. KUNTZ:</p> <p>2 Q. Okay. We'll go through each one, Doctor.</p> <p>3 Do you believe that it's below the standard of care</p> <p>4 to place a Prosimra for a primary repair?</p> <p>5 A. It would depend -- it would actually depend</p> <p>6 on the patient characteristics, and if you had</p> <p>7 somebody that had a connective tissue disorder, it</p> <p>8 might be warranted.</p> <p>9 I feel that in most instances that using</p> <p>10 either a native tissue repair, there would be other</p> <p>11 people that would consider sacrocolpopexy as a</p> <p>12 repair, but I think that has to be individualized</p> <p>13 between the surgeon and the patient. So there will</p> <p>14 always be instances where I cannot say a blanket</p> <p>15 statement.</p> <p>16 Q. Okay.</p> <p>17 A. I just --</p> <p>18 Q. Same answer for Prolift?</p> <p>19 A. Yes.</p> <p>20 Q. Same answer for Prolift+M?</p> <p>21 A. Yes.</p> <p>22 Q. Ethicon paid you to do a study on TVT</p> <p>23 Secur, correct?</p> <p>24 A. That is correct.</p> <p>25 Q. Okay. And they provided the product for</p>	<p style="text-align: center;">Page 48</p> <p>1 Society recommends three to five years.</p> <p>2 MR. KUNTZ: Let's take -- can we take</p> <p>3 a quick break?</p> <p>4 MR. SNELL: Sure.</p> <p>5 THE WITNESS: Okay.</p> <p>6 (10:26 a.m. to 10:35 a.m. -</p> <p>7 Recess taken.)</p> <p>8 (Exhibit No. 1 marked for</p> <p>9 identification.)</p> <p>10 BY MR. KUNTZ:</p> <p>11 Q. Doctor, I'm going to that hand you what's</p> <p>12 been marked Exhibit No. 1. Have you seen this</p> <p>13 document?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Did you review the document request</p> <p>16 in Schedule A on Page 5 of this document?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And you brought some documents that</p> <p>19 we'll go through and mark later that are here on the</p> <p>20 table.</p> <p>21 Did you look at all of these and bring</p> <p>22 responsive documents that you have?</p> <p>23 A. Yeah, any ones that I have, but I don't</p> <p>24 have most of these.</p> <p>25 Q. Okay. Well, let's go through -- let's go</p>
<p style="text-align: center;">Page 47</p> <p>1 free?</p> <p>2 A. Yes, they did.</p> <p>3 Q. And you reported positive findings for the</p> <p>4 TVT Secur?</p> <p>5 A. Yes, I did.</p> <p>6 Q. Why didn't you present the five-year data</p> <p>7 from the TVT Secur?</p> <p>8 A. The -- actually, did I present -- the</p> <p>9 design of the study was actually a six-month study,</p> <p>10 and then I continued to have contact with these</p> <p>11 patients and followed up with UDI scores over a</p> <p>12 longer term. That was outside of the study; it was a</p> <p>13 continuation that was funded by myself.</p> <p>14 Q. Okay. So the study was only designed to be</p> <p>15 a six-month study?</p> <p>16 A. It was a feasibility study, could it be</p> <p>17 done.</p> <p>18 Q. Did it track complications?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. Couldn't track long-term</p> <p>21 complications, could it?</p> <p>22 A. It was not designed for that effect.</p> <p>23 Q. Okay. How long does a study have to be to</p> <p>24 track long-term complications, in your mind?</p> <p>25 A. Ideally, the International Continence</p>	<p style="text-align: center;">Page 49</p> <p>1 through it.</p> <p>2 Obviously, you brought your CV.</p> <p>3 A. Yes.</p> <p>4 Q. Okay. Did you bring all of the documents</p> <p>5 that were provided to you or which were used to form</p> <p>6 your opinions?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And that's in the notebook and on</p> <p>9 the thumb drive?</p> <p>10 A. Yes.</p> <p>11 Q. And some loose-leaf studies that we have</p> <p>12 here?</p> <p>13 A. Yes. And some of them are repetitions.</p> <p>14 Q. No. 5, you haven't reviewed any depositions</p> <p>15 in this case, have you?</p> <p>16 A. I have been provided depositions from the</p> <p>17 plaintiffs, and -- I don't remember. Is it Blaivas?</p> <p>18 MR. SNELL: Just tell him -- you have</p> <p>19 to answer his questions to the best of your ability,</p> <p>20 so tell him what depositions you reviewed. That's what</p> <p>21 he's looking for.</p> <p>22 THE WITNESS: Okay.</p> <p>23 BY MR. KUNTZ:</p> <p>24 Q. Okay. Well, let me ask you this. I didn't</p> <p>25 see any depositions. I don't -- it's unclear, but on</p>

## Michael P. Woods, M.D.

Page 50	Page 52
<p>1 your reliance list, there's not any depositions  2 listed but maybe a deposition of Gene Kammerer. Do  3 you know who Gene Kammerer is?</p> <p>4 A. No.</p> <p>5 Q. Okay. Did you review a deposition of Gene  6 Kammerer?</p> <p>7 A. Not that I recall.</p> <p>8 Q. Okay. Did you review any depositions of  9 any Ethicon employees?</p> <p>10 A. Not that I recall.</p> <p>11 Q. Okay. What depositions did you review  12 prior to today?</p> <p>13 A. Blaivas, Elliott. What's the guy in  14 Chicago? Ro--</p> <p>15 Q. Rosenzweig.</p> <p>16 A. Yeah, Rosenzweig. And Marc Toglia.</p> <p>17 Q. And have you provided all of your time  18 sheets to defense counsel in this case?</p> <p>19 A. Yes, I have.</p> <p>20 Q. How much time have you spent reviewing this  21 case?</p> <p>22 A. About 100 hours.</p> <p>23 Q. That includes up to today?</p> <p>24 A. No.</p> <p>25 Q. Okay. What does the 100 hours include?</p>	<p>1 is.</p> <p>2 THE WITNESS: I--</p> <p>3 MR. SNELL: Only give him your honest  4 answer--</p> <p>5 THE WITNESS: I--</p> <p>6 MR. SNELL: Hold on, listen. Listen,  7 Dr. Woods. You're here to answer his questions  8 honestly and truthfully to the best of your ability  9 and knowledge. You do that. If you don't know  10 something, you tell him, "I don't know," but answer  11 his questions to the best of your knowledge and  12 recollection.</p> <p>13 THE WITNESS: Two or three times.</p> <p>14 BY MR. KUNTZ:</p> <p>15 Q. There's-- I can only dream of the day that  16 I get to depose Burt, but it probably will never  17 happen.</p> <p>18 MR. SNELL: I might be deposing you.  19 You would be in trouble.</p> <p>20 MR. KUNTZ: We can only dream, but...</p> <p>21 THE WITNESS: Okay.</p> <p>22 BY MR. KUNTZ:</p> <p>23 Q. Okay. So two or three days.  24 How many phone calls did you have?  25 A. One phone call.</p>
<p style="text-align: center;">Page 51</p> <p>1 A. Reviews of when I took my board review  2 course, looking through textbooks, going through old  3 documents, old publications, trying to find different  4 things. I've been reviewing this literature since  5 1987, '88, in a continuous fashion and going through  6 and trying to find older documents on why I did the  7 Burch and these kind of things.</p> <p>8 Q. Okay. How many times have you met with  9 defense counsel on this case?</p> <p>10 A. Is it twice or three times? Two or three  11 times. I'm not sure-- I'm trying to remember.  12 It would be three times--</p> <p>13 Q. Okay. Were these all-day meetings?</p> <p>14 A. --face-to-face.</p> <p>15 No.</p> <p>16 Q. Okay. Half-day meetings?</p> <p>17 A. The first time was a half-day, yesterday  18 was a half-day. It-- I need to ask.</p> <p>19 THE WITNESS: I believe I've met with  20 you three times. I don't--</p> <p>21 MR. SNELL: You have to-- hold on.  22 You have to answer his questions. He's-- don't  23 worry about--</p> <p>24 THE WITNESS: Okay.</p> <p>25 MR. SNELL: --what my recollection</p>	<p style="text-align: center;">Page 53</p> <p>1 Q. Okay. So you only talked to defense  2 counsel one time, over the phone?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. And you provided-- so you spent  5 100-- and I apologize if I asked, but you spent 100  6 hours or submitted a bill for 100 hours?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And that-- does that include your  9 meeting yesterday?</p> <p>10 A. No.</p> <p>11 Q. Okay. Does it include the previous  12 meetings?</p> <p>13 A. That would be-- I believe that that was on  14 the day two, September 25th.</p> <p>15 Q. Okay. So since September 25th, you've  16 had one meeting with defense counsel?</p> <p>17 A. That is correct.</p> <p>18 Q. Okay. And how much other time, besides the  19 meeting, have you spent since September 25th  20 preparing for this deposition?</p> <p>21 A. I would have to look on my cheat sheet,  22 which I don't have with me.</p> <p>23 Q. Okay. Do you keep your cheat sheets?</p> <p>24 A. I just write down, and when I submit, toss.  25 And then I'm just trying to keep a record.</p>

Michael P. Woods, M.D.

Page 54	Page 56
<p>1 Q. Okay.</p> <p>2 A. I'm trying to be very honest on how much</p> <p>3 time I spend.</p> <p>4 Q. Okay.</p> <p>5 A. And so if I have a 15-minute break and I</p> <p>6 look at something that's pertinent to this, I will do</p> <p>7 that. I have a very busy practice and, also, I've</p> <p>8 assumed some other positions recently, and so my time</p> <p>9 has been very scattered over the --</p> <p>10 Q. Okay.</p> <p>11 A. -- last couple of weeks.</p> <p>12 Q. Do you keep -- do you -- do you still have</p> <p>13 your -- what you call your cheat sheet for your 100</p> <p>14 hours up to September 25th?</p> <p>15 A. No, I do not.</p> <p>16 Q. Okay. You do have your cheat sheet from</p> <p>17 September 25th to today?</p> <p>18 A. I have multiple little sheets somewhere --</p> <p>19 Q. Okay. All right.</p> <p>20 A. -- either at home or at work.</p> <p>21 Q. We can get a copy of those, can't we?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Just ballpark, how many hours do you</p> <p>24 think you've spent since your 100 hours</p> <p>25 September 25th bill and this morning?</p>	<p>1 malpractice case?</p> <p>2 A. Actually, it was a personal injury case.</p> <p>3 Q. Involving -- is that the car wreck case?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. That's the one you've listed on</p> <p>6 your --</p> <p>7 A. Yes.</p> <p>8 Q. -- on your report?</p> <p>9 A. In all honesty, I don't try to do this</p> <p>10 stuff.</p> <p>11 Q. Have you -- look at No. 12.</p> <p>12 A. Let me get my glasses here. I apologize.</p> <p>13 Q. No. 12 on Page 7 of the notice.</p> <p>14 MR. SNELL: Oh.</p> <p>15 MR. KUNTZ: I'm sorry. Do you need a</p> <p>16 copy?</p> <p>17 MR. SNELL: No, just -- okay.</p> <p>18 THE WITNESS: Okay.</p> <p>19 BY MR. KUNTZ:</p> <p>20 Q. You've been a consultant for Ethicon for</p> <p>21 many years, correct?</p> <p>22 A. Yes, I have.</p> <p>23 Q. Okay. Did you attempt to bring any of the</p> <p>24 consulting agreements you have with Ethicon?</p> <p>25 A. I don't have any of those. When I moved my</p>
<p style="text-align: center;">Page 55</p> <p>1 A. I'm going to ballpark: Probably 15 to 20</p> <p>2 hours.</p> <p>3 Q. Okay. And what do you charge an hour?</p> <p>4 A. In this here, because I -- let me go here</p> <p>5 because I don't pay the most attention. I believe it</p> <p>6 is \$550 an hour.</p> <p>7 Q. Is that across the board for record review</p> <p>8 and deposition time?</p> <p>9 A. Deposition time is \$650 an hour.</p> <p>10 Q. Okay. And what's trial time?</p> <p>11 A. \$4,000 per day.</p> <p>12 Q. Okay. Does that include expenses, or are</p> <p>13 expenses separate?</p> <p>14 A. The answer is, I haven't thought about it.</p> <p>15 Q. Okay. Have you ever testified at trial?</p> <p>16 A. I have testified at one trial.</p> <p>17 Q. Okay. What type of case was that?</p> <p>18 A. That was an overactive bladder case after a</p> <p>19 back injury.</p> <p>20 Q. Okay. Were you an expert witness in that</p> <p>21 case or a defendant?</p> <p>22 A. I was for the plaintiff.</p> <p>23 Q. Where was that case pending?</p> <p>24 A. That was in Nebraska City.</p> <p>25 Q. And I'm sorry if I asked. Was it a medical</p>	<p style="text-align: center;">Page 57</p> <p>1 office, any of those that were old, I tossed out.</p> <p>2 Q. Okay. When did you move your office?</p> <p>3 A. 2013.</p> <p>4 Q. Okay. So do you have the ones from 2014</p> <p>5 and '15?</p> <p>6 A. I'm not a consultant. I don't remember the</p> <p>7 last time that I've worked with Ethicon. It was</p> <p>8 probably 2013. I am not -- I am not exactly sure on</p> <p>9 that.</p> <p>10 Q. So you haven't received any payments,</p> <p>11 non-litigation, as a consultant, from Ethicon in 2013</p> <p>12 or '14?</p> <p>13 A. I believe in 2013 I did one -- one or two</p> <p>14 educational things for sales staff.</p> <p>15 Q. Okay.</p> <p>16 A. But I don't recall 2014, to be very honest</p> <p>17 with you.</p> <p>18 Q. So you did consult with them in 2013?</p> <p>19 A. First part, yes.</p> <p>20 Q. Okay. In 2014, it's your testimony that</p> <p>21 you did not consult with Ethicon?</p> <p>22 A. I do not recall having a consulting</p> <p>23 agreement with Ethicon.</p> <p>24 Q. Okay. Well, on your CV, it says, Consult</p> <p>25 for Johnson &amp; Johnson, Ethicon's Women's Health and</p>

## Michael P. Woods, M.D.

Page 58	Page 60
<p>1     Urology, 2004 to 2014?</p> <p>2     A. The first part of 2000 (sic), so January 1.</p> <p>3     Q. Okay.</p> <p>4     A. I don't know when the last consulting</p> <p>5     agreement ended, but I think it was the end of 2013.</p> <p>6     Q. Okay. So you haven't done anything in that</p> <p>7     calendar year 2014 for Johnson &amp; Johnson?</p> <p>8     A. Not that I recall.</p> <p>9     Q. Okay.</p> <p>10    A. There might have been -- I'm -- between</p> <p>11  2013/2014, I'm not -- I know I went back at some time</p> <p>12  in that time to do a teaching course for sales</p> <p>13  staff --</p> <p>14  Q. Okay.</p> <p>15  A. -- but I don't recall when.</p> <p>16  Q. So it's possible it was in 2014?</p> <p>17  A. It's possible. I just don't quite recall.</p> <p>18  Q. And you don't keep records of any of that</p> <p>19  stuff?</p> <p>20  A. No. Any payments that I receive from</p> <p>21  Johnson &amp; Johnson went right to the corporation.</p> <p>22  Q. Okay. What corporation?</p> <p>23  A. That was Bellevue Obstetrics and</p> <p>24  Gynecology.</p> <p>25  Q. Why did that company dissolve?</p>	<p>1     were a consultant for Ethicon from 2004 to 2014. Do</p> <p>2     you remember that?</p> <p>3     A. Yes.</p> <p>4     Q. In fact, you started consulting with them</p> <p>5     in 2002, didn't you?</p> <p>6     A. I don't remember the exact time.</p> <p>7     Q. Okay. Possible it was before 2004?</p> <p>8     A. Yes.</p> <p>9     Q. So you've never kept any of your billing</p> <p>10  records or payments you've received from Ethicon with</p> <p>11  your consulting agreements?</p> <p>12  A. No.</p> <p>13  Q. Okay. You got rid of all of those when you</p> <p>14  moved offices in 2013?</p> <p>15  A. Yes.</p> <p>16  Q. Do you keep any of your professional</p> <p>17  education or PowerPoints or presentations you've done</p> <p>18  for Ethicon?</p> <p>19  A. I have kept -- I couldn't find a lot of</p> <p>20  them, and a lot of them were on a computer that was</p> <p>21  destroyed when I was traveling cross-country.</p> <p>22  Q. Okay.</p> <p>23  A. And so --</p> <p>24  Q. When was that?</p> <p>25  A. That was right around 2013, or so. It's</p>
<p>1     A. Because I moved to Shenandoah and took a</p> <p>2     position with the hospital.</p> <p>3     Q. Okay. Did you do anything in between those</p> <p>4     two jobs?</p> <p>5     A. I worked -- I actually balanced two jobs</p> <p>6     there for a while, where I took a position at ICON</p> <p>7     Clinical Resources trying to learn how to do studies</p> <p>8     better.</p> <p>9     Q. And did you practice medicine during that</p> <p>10  time?</p> <p>11  A. Yes, I did.</p> <p>12  Q. Okay. Where at?</p> <p>13  A. Bellevue Obstetrics and Gynecology and my</p> <p>14  rural outreach clinics.</p> <p>15  Q. And so Bellevue obstetrical was still open</p> <p>16  during the time you were at ICON?</p> <p>17  A. Yes, it was.</p> <p>18  Q. Okay. Did you have partners in that</p> <p>19  business?</p> <p>20  A. No.</p> <p>21  Q. Okay. You were a solo practitioner?</p> <p>22  A. With a PA.</p> <p>23  Or between 2001 and 2003 I had two</p> <p>24  partners.</p> <p>25  Q. We just looked at your CV and it says you</p>	<p>1     one of those that I wish I would have taken the</p> <p>2     computer out or had a curbside -- or check it at the</p> <p>3     door. And it looked like someone had run over it; it</p> <p>4     was literally destroyed.</p> <p>5     Q. So did you do a search for -- you said you</p> <p>6     found some of those presentations?</p> <p>7     A. Yes. I --</p> <p>8     Q. Are those on the thumb drive?</p> <p>9     MR. SNELL: Paul, are those on -- are</p> <p>10  those on the thumb drive, Paul, or do you know?</p> <p>11  MR. ROSENBLATT: No, they're not on</p> <p>12  the thumb drive.</p> <p>13  MR. SNELL: Do we have them print out?</p> <p>14  MR. ROSENBLATT: Yeah, I've got --</p> <p>15  MR. SNELL: Tell him if you were able</p> <p>16  to find some of them.</p> <p>17  THE WITNESS: A lot of them I just --</p> <p>18  I know were on the computer that was destroyed.</p> <p>19  MR. SNELL: No. He asked you which</p> <p>20  ones did you find.</p> <p>21  BY MR. KUNTZ:</p> <p>22  Q. Let me ask you this. The ones you found</p> <p>23  you forwarded to counsel?</p> <p>24  A. Yes, I have.</p> <p>25  Q. Okay. And --</p>

Michael P. Woods, M.D.

Page 62	Page 63	Page 65
<p>1 MR. KUNTZ: I just wanted to know if 2 they existed.</p> <p>3 MR. SNELL: Just let the record 4 reflect we handed counsel a folder with numerous 5 PowerPoint presentations inside there. All right.</p> <p>6 MR. KUNTZ: I'll look at those later.</p> <p>7 BY MR. KUNTZ:</p> <p>8 Q. Have you ever -- how many clinical trials 9 or studies have you participated in for Ethicon? We 10 talked about the TVT Secur.</p> <p>11 A. Secur. I believe with Ethicon that was the 12 only one where I was a PI.</p> <p>13 Q. Okay. Did you keep any of the documents 14 from the TVT Secur study?</p> <p>15 A. Yes. I would have to find where they're 16 at, but yes.</p> <p>17 Q. Okay. And can you provide those to defense 18 counsel?</p> <p>19 A. I would have to look through a lot of 20 boxes, but I believe that I can provide that to 21 counsel.</p> <p>22 Q. Have you ever participated as an 23 investigator for any other device companies related 24 to pelvic floor products?</p> <p>25 A. Yes. With Coloplast, with their Altis</p>	<p>1 A. It was just kind of a blanket consulting. 2 That hasn't gone anywhere.</p> <p>3 Q. Okay. Do you have a current consulting 4 agreement with Coloplast?</p> <p>5 A. I believe I do. I would have to find that, 6 but I can -- I believe I could find it.</p> <p>7 Q. When did you first start consulting with 8 Coloplast?</p> <p>9 A. I'm unsure.</p> <p>10 Q. Why did you stop consulting with Ethicon in 11 the last year?</p> <p>12 A. They didn't offer any consulting 13 agreements.</p> <p>14 Q. Okay. Did you ask them why?</p> <p>15 A. No.</p> <p>16 Q. When did they first contact you to be an 17 expert witness in this case?</p> <p>18 A. I believe in July of this year.</p> <p>19 Q. Who called you?</p> <p>20 A. Paul Rosenblatt.</p> <p>21 Q. So prior to your involvement in this case, 22 you had been a consultant for Ethicon for at least 23 ten years?</p> <p>24 A. Yes.</p> <p>25 Q. I'm going to -- let's mark your report as</p>	<p>1 Exhibit 2. 2 (Exhibit No. 2 marked for 3 identification.)</p> <p>4 BY MR. KUNTZ:</p> <p>5 Q. Doctor, this is just for the record. You 6 can refer.</p> <p>7 A. Okay.</p> <p>8 Q. I'm just marking this --</p> <p>9 MR. SNELL: That's okay.</p> <p>10 BY MR. KUNTZ:</p> <p>11 Q. -- to have it marked. You can use your 12 copy of it.</p> <p>13 This is your signature at the end of this 14 report, correct?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. Do you stand by all of the 17 statements you made in this report?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Did you review this report yesterday 20 in preparation for the deposition?</p> <p>21 A. Yes.</p> <p>22 Q. Anything you want to correct in the report?</p> <p>23 A. I would have to go to one -- can I look 24 through this a second?</p> <p>25 Q. Sure.</p>

Michael P. Woods, M.D.

Page 66	Page 68
<p>1       A. This is one that I found. This may take 2       me -- I did not mark it in here, so it may take me a 3       moment.</p> <p>4       Q. Take your time.</p> <p>5       A. This may take me a few moments. Do you 6       want to --</p> <p>7       Q. We'll do it on a lunch break, or something. 8       We can do that.</p> <p>9       A. I'll look through this because I'm trying 10      to find it and I --</p> <p>11      Q. Okay. But it sounds like there's something 12      that you wanted to correct and you're going to look 13      through it at a break --</p> <p>14      A. Yes.</p> <p>15      Q. -- and let me know?</p> <p>16      A. Yes.</p> <p>17      Q. Okay. How long did it take you to write 18      this report?</p> <p>19      A. That -- this was a chunk of that 100 hours.</p> <p>20      Q. Okay. How many?</p> <p>21      A. In writing this report, I would probably 22      say 35 to 40 hours of that time, and I'm just taking 23      a ballpark estimate.</p> <p>24      Q. Okay.</p> <p>25      A. That's just the writing and going over it.</p>	<p>1       A. I -- I have to look at the data that I was 2       asked to look at, which was higher level.</p> <p>3       Q. Okay.</p> <p>4       A. And --</p> <p>5       Q. So is testimony of the Ethicon employees 6       not important to you in forming your opinions in this 7       case?</p> <p>8       A. No.</p> <p>9       Q. Okay. You know David Robinson, right?</p> <p>10      A. Yes, I do.</p> <p>11      Q. You communicate with him -- or you did 12      communicate with him a lot during your consulting 13      days with Ethicon, correct?</p> <p>14      A. Yes.</p> <p>15      Q. Okay. It's not important to you what David 16      Robinson said about the development or issues related 17      to the TVT Retropubic?</p> <p>18      A. No.</p> <p>19      Q. Who put together the literature list in 20      your reliance list?</p> <p>21      A. This was my own. This was going looking at 22      the various studies, doing the list.</p> <p>23      Q. Okay.</p> <p>24      A. And so if I were going through and found an 25      article that referred to an article, then I would try</p>
<p style="text-align: center;">Page 67</p> <p>1       It's not the review.</p> <p>2       Q. Did you prepare the Attachment C, the 3       exhibit list? Actually, it might be B.</p> <p>4       MR. ROSENBLATT: You're referring to 5       the reliance list?</p> <p>6       BY MR. KUNTZ:</p> <p>7       Q. Yeah, the reliance list. I'm sorry.</p> <p>8       A. Yeah, my reliance list.</p> <p>9       Q. Is Exhibit -- strike that.</p> <p>10      A. Yes.</p> <p>11      Q. Did you prepare Exhibit B, the reliance 12      list?</p> <p>13      A. Yes.</p> <p>14      Q. So you put this together?</p> <p>15      A. This is a list of everything that I looked 16      through and relied upon.</p> <p>17      Q. Did you ask for any internal documents, or 18      were they just provided to you by defense counsel?</p> <p>19      A. Provided by the defense counsel.</p> <p>20      Q. Okay. Did you ever ask for any deposition 21      testimony of any Ethicon employees?</p> <p>22      A. No.</p> <p>23      Q. Okay. It's not important to you what some 24      of the internal employees say about some of the 25      issues of this lawsuit?</p>	<p style="text-align: center;">Page 69</p> <p>1       to find that.</p> <p>2       Q. Okay. Did you type this reliance list 3       yourself?</p> <p>4       A. No, I did not.</p> <p>5       MR. SNELL: No. I will state, for the 6       record, that is something that our paralegals typed.</p> <p>7       BY MR. KUNTZ:</p> <p>8       Q. Did you provide them with all of the 9       articles that are on this list --</p> <p>10      A. Yes.</p> <p>11      Q. -- for the literature?</p> <p>12      Okay. So did they provide you -- did 13      defense counsel provide you with any articles?</p> <p>14      A. Yes, they provided me with articles, and I 15      provided them with other articles that I felt would 16      support this.</p> <p>17      Q. So this was -- this list was put together 18      kind of jointly --</p> <p>19      A. Yes.</p> <p>20      Q. -- with respect to the literature?</p> <p>21      A. Yes. It's a massive -- there's no way to 22      get through all of that literature easily.</p> <p>23      Q. So what kind of searches did you do for 24      literature?</p> <p>25      A. I did PubMed searches. I also looked at</p>

Michael P. Woods, M.D.

Page 70	Page 72
<p>1 the systemic reviews, and then I would pull up 2 articles they cited that I felt were relevant. 3 I tried to weed out as best I could on the 4 level of data--it's just -- it's overwhelming when 5 you have over 2,000 articles--and just try to create 6 the levels within the pyramid of what I felt was a 7 higher-level data.</p> <p>8 Q. Did you read all 2,000 articles?</p> <p>9 A. I skimmed through many articles. I can't 10 say exactly how many.</p> <p>11 Q. Okay. Ballpark guess?</p> <p>12 A. Honestly, I don't have a whole lot of idea.</p> <p>13 I then would go to the meta-analysis and 14 then also the systemic reviews in order to be able to 15 condense it down. I didn't want to repeat a lot of 16 the work that had been done.</p> <p>17 Q. All right. How many hours did you spend 18 reviewing the internal documents that are cited on 19 your reliance list?</p> <p>20 A. I would probably -- this is, again, going 21 to be a ballpark. Probably about ten hours.</p> <p>22 Q. Okay. I also noticed that you reviewed 23 several of the plaintiffs' expert reports.</p> <p>24 A. Yes.</p> <p>25 Q. Did you review those in detail?</p>	<p>1 A. They were not -- I'm not -- part of theirs 2 was related to hernia mesh, animal data, these kind 3 of things. I was looking at some of the level of 4 evidence and then looking at how they presented it.</p> <p>5 Q. Okay. Did you -- so you didn't review any 6 of the plaintiffs' experts' reliance materials that 7 were attached to their reports, correct?</p> <p>8 A. If it -- I shared many of the same 9 documents that I had already reviewed.</p> <p>10 Q. Okay. But if they were different ones that 11 aren't on your reliance list and they're on the 12 plaintiffs' expert reports, did you review those?</p> <p>13 A. There were some that I did review, yes.</p> <p>14 Q. Okay. Did you make a note of which ones 15 you did and didn't review?</p> <p>16 A. No, I did not.</p> <p>17 Q. Okay. Were those printed out for you, all 18 of the plaintiffs' documents that are on the 19 plaintiffs' experts' reliance reports?</p> <p>20 A. I reviewed over what the reference lists 21 were, and then --</p> <p>22 Q. Okay.</p> <p>23 A. -- looked at -- there was overlap with what 24 I had already reviewed, so --</p> <p>25 Q. Okay. My -- that's not my question. So</p>
<p style="text-align: center;">Page 71</p> <p>1 A. I reviewed over trying to get the gist of 2 what they were saying, so -- on the expert reports, 3 and then in the -- reading the depositions was more 4 going through. I don't understand all of the 5 legalese, and so --</p> <p>6 Q. Okay. Did you -- did you review any of the 7 exhibits to the depositions?</p> <p>8 A. I don't recall -- no.</p> <p>9 Q. How long did you spend reviewing the 10 plaintiffs' expert reports that are listed on your 11 reliance list?</p> <p>12 A. I would say about an hour -- you know, on 13 what they were saying, about an hour a piece. I 14 would read them a lot like I would an article.</p> <p>15 Q. Okay. Did you review all of the footnotes 16 that are cited in the plaintiffs' expert reports?</p> <p>17 A. No.</p> <p>18 Q. Okay. You didn't pull those documents and 19 look at them, did you?</p> <p>20 A. No. Most of the documents were not related 21 to -- they were hernia mesh. They weren't -- they 22 weren't related to what I was asked to review.</p> <p>23 Q. Okay. So you -- it's your testimony that 24 most of the documents in the plaintiffs' expert 25 reports related to hernia mesh?</p>	<p style="text-align: center;">Page 73</p> <p>1 some of the documents on the plaintiffs' expert 2 reports are the same as you have on your reliance 3 list, right?</p> <p>4 A. Yes.</p> <p>5 Q. And there are different ones, as well, 6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. Did you review the actual documents?</p> <p>9 A. As -- as in articles?</p> <p>10 Q. Articles? Internal documents?</p> <p>11 A. Many of the internal documents I did not 12 pay credence to because it would not affect the 13 evidence that I was asked to look at.</p> <p>14 Q. So you didn't actually pull the documents 15 or ask to be sent the documents in the plaintiffs' 16 expert reports to review them, correct?</p> <p>17 A. Correct.</p> <p>18 Q. Okay. You just reviewed the reports and 19 the body of the reports and not the documents cited 20 or not the documents on the reliance list that were 21 different than the ones you'd reviewed for your 22 report --</p> <p>23 MR. SNELL: Objection, form.</p> <p>24 BY MR. KUNTZ:</p> <p>25 Q. -- correct?</p>

Michael P. Woods, M.D.

Page 74	Page 76
<p>1        A. What I did is if there was overlap -- there  2        was such a huge amount of data there, so when it came  3        to, say, internal documents, I -- or -- I didn't have  4        access to e-mails or anything along this line, so on  5        those, what I was doing is looking at level of  6        evidence, so was this a randomized controlled study,  7        was this in a systemic review, these kinds of things.  8        Q. Right. But you didn't look at the actual  9        documents, correct?  10      A. Correct.  11      MR. SNELL: Objection, form.  12      BY MR. KUNTZ:  13      Q. Okay. And you didn't look at any of, say,  14       the internal documents of Ethicon that are cited in  15       the plaintiffs' expert reports, you didn't review  16       those actual documents?  17      A. I did not feel that it would impact my  18       viewpoint because I was relying on top-level data.  19      Q. So the answer to my question is, no, you  20       did not review them?  21      A. If I did, it would have been very briefly  22       as in a quick skim.  23      Q. Okay. All right. Who printed those  24       documents off for you?  25      A. Those are received from plaintiffs'</p>	<p>1        A. -- the in-depth review. Some I skimmed,  2        some I looked at more closely, yes.  3        Q. Okay. How long did you spend reviewing all  4        of the documents that are cited in plaintiffs' expert  5        reports?  6        A. I -- the thing is is that we have to look  7        that a lot of the literature, you know, I've already  8        reviewed because I've been reviewing it for 20-plus  9        years.  10      Q. Let's break it down, internal documents.  11      How long did you spend reviewing internal documents  12       that were cited in plaintiffs' expert reports?  13      A. I'm unsure of an exact amount of time.  14      Q. Who's Nick Jewell?  15      A. I do not know.  16      Q. You don't know that name?  17      A. No.  18      Q. Did you review his expert report?  19      A. If I did, I -- I don't recall.  20      Q. Okay. Who is Howard Jordi?  21      A. I don't recognize that name.  22      Q. Who is Thomas Muehl?  23      A. I don't recognize that name.  24      Q. Did you read Dr. Margolis's expert report  25       in the Carolyn Lewis case?</p>
<p>1        counsel -- or defense counsel.  2        Q. Okay. Were those on your thumb drive?  3        MR. SNELL: They should be.  4        MR. KUNTZ: Okay. So all -- so all of  5        the plaintiffs' expert report reliance materials are  6        on the thumb drive?  7        MR. SNELL: Yes. As far as I know, we  8        sent him all -- every footnoted article or document  9        or thing that was cited by your experts along with  10       their reports; that should be on the thumb drive. If  11       it's not --  12       Do you know if that's on the thumb drive?  13       MR. ROSENBLATT: I haven't checked.  14       If it's not, we'll get that updated, but we'll send  15       him a response.  16       MR. KUNTZ: Hold on. Did you provide  17       them to him or not?  18       MR. SNELL: Yes.  19       THE WITNESS: Yes.  20      BY MR. KUNTZ:  21       Q. Okay. So every document that you reviewed  22       in this case to give your opinions today is on that  23       thumb drive?  24       A. Yes --  25       Q. Okay.</p>	<p>1        A. No, I did not.  2        Q. Did you review any expert reports in the  3        Carolyn Lewis case?  4        A. I'm not familiar with the Carolyn Lewis  5        case.  6        Q. You never heard of the name Carolyn Lewis  7        before today?  8        A. No.  9        Q. So if those expert reports are listed on  10       your reliance list, is it fair to say that you did  11       not review those?  12       A. Or I skimmed them very rapidly.  13       Q. Is it accurate to say that even if you did  14       review any internal documents from plaintiffs' expert  15       reports, they don't have any bearing on your opinions  16       in this case?  17       A. That is correct.  18       Q. Why did you review the internal documents,  19       then, that are on your reliance list?  20       A. As I say, if I looked at them, I listed  21       them.  22       Q. Okay.  23       A. But there's a difference between looking at  24       something in-depth versus going over. Also, I am  25       very poor with names.</p>

## Michael P. Woods, M.D.

Page 78	Page 80
<p>1       Q. Is this the first time you've ever been 2       asked by a medical device company to serve as an 3       expert witness?</p> <p>4       A. Yes.</p> <p>5       Q. Have you ever been an expert in a medical 6       malpractice case?</p> <p>7       A. I have reviewed one case, but that was it.</p> <p>8       Q. Okay. Have you ever been -- strike that.</p> <p>9       Have you ever given depositions in the 10      medical malpractice cases in which you were named as 11      a defendant?</p> <p>12      A. Yes.</p> <p>13      Q. Okay. Did you give a deposition in Bunman 14      v. Woods?</p> <p>15      A. What was the name, again?</p> <p>16      Q. Bunman, B-U-N-M-A-N?</p> <p>17      A. I believe it was Putnam. I don't remember 18      the name.</p> <p>19      Q. Okay. What was the issue in that case?</p> <p>20      A. It's been a long time ago. I -- I don't 21      recall on many of the cases what it -- on that one, I 22      don't have a recollection.</p> <p>23      Q. Okay. What about -- did you give a 24      deposition in Gardener (ph) v. Woods?</p> <p>25      A. Yes.</p>	<p>1       be honest with you. It was 1994 is when it went 2       to --</p> <p>3       Q. Have you kept copies of any of these 4       depositions?</p> <p>5       A. No.</p> <p>6       Q. Were you represented by the same person in 7       all of these cases?</p> <p>8       A. No.</p> <p>9       Q. Have you ever been a party to any other 10      lawsuits?</p> <p>11      A. No, not that I recall.</p> <p>12      Q. Have you ever had any contact with any 13      other Ethicon -- strike that.</p> <p>14      Do you know any of the other experts that 15      have been named by Ethicon in this case?</p> <p>16      A. Yes.</p> <p>17      Q. Okay. Have you talked to them about this 18      case?</p> <p>19      A. Not at all.</p> <p>20      Q. Okay. Do you know them?</p> <p>21      A. Yes, I do.</p> <p>22      Q. Okay. How do you know them?</p> <p>23      A. Professionally, Denise Elser; and then Kim 24      Kenton I know professionally and, also, she and I, on 25      that Gore-Tex mesh, were coauthors.</p>
<p style="text-align: center;">Page 79</p> <p>1       Q. Okay. What about Kutner (ph) v. Woods?</p> <p>2       A. Yes.</p> <p>3       Q. Gray v. Woods?</p> <p>4       A. Yes.</p> <p>5       Q. Okay. Hanson v. Woods?</p> <p>6       A. Yes.</p> <p>7       Q. Okay. What about Bremmer (ph) versus 8       Woods?</p> <p>9       A. I don't recall if I gave a deposition on 10      that one. I don't recall.</p> <p>11      Q. Is that -- was that a suit brought by the 12      government; do you know?</p> <p>13      A. I don't believe so.</p> <p>14      Q. Was Bremmer represented by the U.S. 15      Attorney's Office, do you know?</p> <p>16      A. I don't recall.</p> <p>17      Q. Okay. Do you -- did any of these medical 18      malpractice cases involve issues related to stress 19      urinary incontinence?</p> <p>20      A. No.</p> <p>21      Q. Okay. What about pelvic floor disorder?</p> <p>22      A. There was one vesicovaginal fistula, but 23      that was after a hysterectomy.</p> <p>24      Q. Okay. Which was one was that?</p> <p>25      A. I don't remember the name of the patient to</p>	<p style="text-align: center;">Page 81</p> <p>1       Q. Have you ever had any actions taken against 2       your medical license?</p> <p>3       A. No.</p> <p>4       Q. Okay. Any Orders of Compliance?</p> <p>5       A. Yes.</p> <p>6       Q. Okay. What was that?</p> <p>7       A. That was a case where I was at Jennie 8       Edmundson Hospital and a patient of mine showed up at 9       a hospital I did not have privileges. They tried to 10      contact me and I was in the basement of the office. 11      They were unable. I didn't have cell phone service. 12      They transferred the patient to the University of 13      Nebraska. The University of Nebraska had just 14      switched from a Rolodex call schedule to computer, 15      but they had not done it for the private physicians, 16      and they were using old contact data.</p> <p>17      Q. Okay.</p> <p>18      A. That actually was from my residency several 19      years before and they were unable to get ahold of me.</p> <p>20      Q. Did the licensing department of Nebraska 21      issue an order on that case?</p> <p>22      A. They issued an Order of Compliance with 23      no -- I want to say penalties, but that's not the 24      right word. But I -- what I did is I cooperated and 25      acknowledged they couldn't get ahold of me, and so</p>

## Michael P. Woods, M.D.

<p style="text-align: right;">Page 82</p> <p>1 there was no restrictions.</p> <p>2 Q. When was that?</p> <p>3 A. I think the incident happened in 2007 and</p> <p>4 that came out I believe in 2009, but I'm not exactly</p> <p>5 sure.</p> <p>6 Q. Okay. Anything else?</p> <p>7 A. No.</p> <p>8 Q. Have you ever completed a fellowship in</p> <p>9 urogynecology?</p> <p>10 A. No.</p> <p>11 Q. Did you apply to fellowship programs?</p> <p>12 A. No, I did not.</p> <p>13 Q. Okay. Do you know now if you can become a</p> <p>14 urogynecologist without going through a fellowship?</p> <p>15 A. After 2015, no, you cannot.</p> <p>16 Q. And so you call yourself a urogynecologist</p> <p>17 because you passed what board?</p> <p>18 A. I am board certified in both obstetrics and</p> <p>19 gynecology and female pelvic medicine and</p> <p>20 reconstructive surgery.</p> <p>21 Q. When did you take that test?</p> <p>22 A. 2013. It was the first year that it was</p> <p>23 available.</p> <p>24 Q. Do you practice both in Nebraska and Iowa?</p> <p>25 A. I now practice in Iowa. I have a license</p>	<p style="text-align: right;">Page 84</p> <p>1 May when they closed the office.</p> <p>2 Q. Okay. So ICON -- where was ICON Clinical</p> <p>3 Services located?</p> <p>4 A. Actually, right across over here</p> <p>5 (indicating), about 114th.</p> <p>6 Q. And what were your duties there?</p> <p>7 A. When I first went there, it was to become a</p> <p>8 primary investigator, but I was going through the</p> <p>9 training process. I actually wanted to learn how to</p> <p>10 do studies better, and it was the second largest</p> <p>11 Phase I company in the world, and approached them.</p> <p>12 Q. Why did they close?</p> <p>13 A. The corporate office in Dublin decided to</p> <p>14 close the office in Omaha.</p> <p>15 Q. Okay. Why did you want to learn how to do</p> <p>16 studies better?</p> <p>17 A. I felt that in my training, observational</p> <p>18 studies were about the best there was, and the level</p> <p>19 of data had changed during my evolution of my</p> <p>20 professional life, and I wanted to understand the</p> <p>21 business aspect but, also, really, how to do studies</p> <p>22 properly. I don't have the fellowship available to</p> <p>23 me, without having to quit my practice, and I thought</p> <p>24 that this would be one way where I could learn from</p> <p>25 the people that were doing the highest-level research</p>
<p style="text-align: right;">Page 83</p> <p>1 in Nebraska, but I no longer have hospital privileges</p> <p>2 in Nebraska.</p> <p>3 Q. Do you bill for patients in Nebraska?</p> <p>4 A. I have patients that come from Nebraska</p> <p>5 over to Iowa, yes.</p> <p>6 Q. Okay. So you bill Nebraska Medicaid</p> <p>7 program?</p> <p>8 A. Yes, I would say, because I can recall one</p> <p>9 patient that I have had that --</p> <p>10 Q. Is your legal office in Nebraska or Iowa?</p> <p>11 MR. SNELL: Objection, form.</p> <p>12 THE WITNESS: My legal --</p> <p>13 BY MR. KUNTZ:</p> <p>14 Q. Is -- do you have an office in Nebraska any</p> <p>15 longer?</p> <p>16 A. No, I do not.</p> <p>17 Q. Okay. Do you have two separate companies</p> <p>18 or just one?</p> <p>19 A. I don't have a company anymore. I'm</p> <p>20 employed.</p> <p>21 Q. Okay. And you're an employee of?</p> <p>22 A. Shenandoah Community Hospital.</p> <p>23 Q. How long did you work at ICON Clinical</p> <p>24 Services?</p> <p>25 A. Six months. At the end of November until</p>	<p style="text-align: right;">Page 85</p> <p>1 for the federal government.</p> <p>2 Q. Okay. Did you decide to -- after they</p> <p>3 closed down, to take up that endeavor any further?</p> <p>4 A. No. I -- the opportunity arose in</p> <p>5 Shenandoah to align with exactly what I was looking</p> <p>6 for.</p> <p>7 Q. Did you work on polypropylene mesh while</p> <p>8 you were at ICON?</p> <p>9 A. No, I did not.</p> <p>10 Q. Did you work on SUI products while you were</p> <p>11 there?</p> <p>12 A. No, I did not.</p> <p>13 Q. Did you work on TVT while you were there?</p> <p>14 A. No, I did not.</p> <p>15 Q. Did you work on any mesh products?</p> <p>16 A. In research?</p> <p>17 Q. Uh-huh.</p> <p>18 A. No, I did not.</p> <p>19 Q. I saw in your CV that you written an</p> <p>20 article with Linda Brubaker?</p> <p>21 A. That was the -- the Kenton that I had</p> <p>22 mentioned earlier, Linda Brubaker was also on that.</p> <p>23 Q. She was Dean at the medical school you were</p> <p>24 trained at, correct?</p> <p>25 A. That is correct.</p>

## Michael P. Woods, M.D.

Page 86	Page 88
<p>1       Q. Okay. She's one of the most respected 2       pelvic floor surgeons in the world?</p> <p>3       A. I have a tremendous respect for Linda, yes.</p> <p>4       Q. And do you agree that she has more 5       experience and expertise in pelvic floor surgery than 6       you?</p> <p>7            MR. SNELL: I'm going to object, lacks 8       foundation.</p> <p>9            THE WITNESS: Linda and I share a lot 10      in common.</p> <p>11      BY MR. KUNTZ:</p> <p>12      Q. Okay.</p> <p>13      A. She has done much more research than I 14      have, so she has --</p> <p>15      Q. You agree she --</p> <p>16      THE REPORTER: "She has" --</p> <p>17      THE WITNESS: Done much more research 18      and publication and education.</p> <p>19      BY MR. KUNTZ:</p> <p>20      Q. You would agree that she's an expert in 21      mesh complications, correct?</p> <p>22      A. I believe -- yes, I believe she is an 23      expert in female pelvic floor disorders, yes.</p> <p>24      Q. Are you doing any current research on 25      polypropylene mesh?</p>	<p>1       Q. Was that the same trip?</p> <p>2       A. Yes.</p> <p>3       Q. Okay. Did Ethicon pay for your travel over 4       there?</p> <p>5       A. No, I paid for my travel.</p> <p>6       Q. And Ethicon paid for what for the Taiwan 7       part of the trip?</p> <p>8            A. They -- in the Taiwan part of the trip, 9       they paid for the hotel and my contracted amount. I 10      don't remember what it was.</p> <p>11      Q. Okay. Did they pay for any portion of your 12      airfare?</p> <p>13      A. No, they did not.</p> <p>14      Q. Did they pay for your meals while you were 15      over there?</p> <p>16      A. Yes.</p> <p>17      Q. Okay.</p> <p>18      A. Actually, I am unsure.</p> <p>19      Q. Okay. We'll go through it here in a little 20      bit.</p> <p>21      A. Yes, that I'm unsure because --</p> <p>22      Q. So they did pay for part of your travel on 23      your trip to Hong Kong and Taiwan, correct?</p> <p>24      A. For the Taiwan portion.</p> <p>25      Q. Any other lectures you've ever given,</p>
Page 87	Page 89
<p>1       A. No, I have not.</p> <p>2       Q. Okay. You've never written on 3       polypropylene mesh, correct?</p> <p>4       A. No, I have not.</p> <p>5       Q. Okay. You've never lectured on 6       polypropylene mesh outside of Ethicon, correct?</p> <p>7       A. Yes, I have.</p> <p>8       Q. Okay. Where at?</p> <p>9       A. The Hong Kong Urogyn Association. I 10      believe that was 2009. And the Taiwan Urogyn 11      Association which I also believe was in 2009.</p> <p>12      Q. Did Ethicon pay for you to go on those two 13      trips?</p> <p>14      A. No.</p> <p>15      Q. Okay. You went on --</p> <p>16      A. In 2009 I was invited by the Hong Kong 17      Hospital Authority.</p> <p>18      Q. Did Ethicon have any involvement in that 19      trip to Hong Kong?</p> <p>20      A. No, they did not.</p> <p>21      Q. You received no payments from Ethicon for 22      that trip?</p> <p>23      A. Not -- I did receive payments for the 24      Taiwan side of it but not for the Hong Kong side at 25      all.</p>	<p>1       besides those two, on polypropylene mesh?</p> <p>2            MR. SNELL: Form.</p> <p>3      BY MR. KUNTZ:</p> <p>4            Q. Strike that. Tell me every lecture you've 5       ever given on polypropylene mesh. I thought I asked 6       that, and you said Hong Kong and Taiwan.</p> <p>7            A. No, that would be -- I'm just trying to go 8       back and think. I think that would be correct.</p> <p>9            Q. You've never written on the Burch 10      procedure?</p> <p>11      A. I'm going to -- I am going to go back in 12      that I gave a lecture at University of Missouri, 13      Kansas City, on the post FDA 2012 meeting on pelvic 14      floor mesh. I believe I gave a grand rounds at --</p> <p>15      Q. Ethicon paid for that trip?</p> <p>16      A. No.</p> <p>17      Q. Who invited you to that trip?</p> <p>18      A. The chairman of the department, a 19      perinatologist. I'm blanking on his name right now.</p> <p>20      Q. Did you keep that presentation?</p> <p>21      A. No, I don't have that presentation.</p> <p>22      Q. Was that lost on the computer, too.</p> <p>23      A. That was on my computer.</p> <p>24      Q. What was that lecture about?</p> <p>25      A. That was just reviewing pelvic floor mesh</p>

Michael P. Woods, M.D.

Page 90	Page 92
<p>1 after the FDA meeting in September 2011.</p> <p>2 Q. Okay. You never published anything on the</p> <p>3 Burch procedure, correct?</p> <p>4 A. No.</p> <p>5 Q. You never published or written anything on</p> <p>6 the pubovaginal slings?</p> <p>7 A. No.</p> <p>8 Q. You doing any research on polypropylene</p> <p>9 mesh right now?</p> <p>10 A. No, I'm not.</p> <p>11 Q. You're not an expert in chemical</p> <p>12 engineering?</p> <p>13 A. No, I'm not an expert on chemical</p> <p>14 engineering.</p> <p>15 Q. Not an expert in pathology?</p> <p>16 MR. SNELL: Objection, form.</p> <p>17 THE WITNESS: No.</p> <p>18 BY MR. KUNTZ:</p> <p>19 Q. Are you an expert in pathology?</p> <p>20 A. No. I have taught histology in medical</p> <p>21 school and I have reviewed pathology slides with</p> <p>22 pathologists, but I am not a -- I am not a</p> <p>23 pathologist.</p> <p>24 Q. Okay. When did you teach histology?</p> <p>25 A. In my first year of medical school, I was a</p>	<p>1 obstructive symptoms.</p> <p>2 Q. Okay. Why did you look at that mesh under</p> <p>3 the microscope?</p> <p>4 A. I just wanted to. I asked the pathologist</p> <p>5 and I just wanted to look at it.</p> <p>6 Q. You only wanted to do that one time with</p> <p>7 explanted mesh?</p> <p>8 A. I didn't feel a strong need to continue</p> <p>9 looking. No, just the one time.</p> <p>10 Q. Who was the pathologist?</p> <p>11 A. I don't recall.</p> <p>12 Q. When was this?</p> <p>13 A. Several years. I couldn't give you a year</p> <p>14 to be honest with you.</p> <p>15 Q. You're not a biomaterials expert?</p> <p>16 A. I -- I -- as I say, I've implanted, but I</p> <p>17 would not consider -- call myself a biomaterials</p> <p>18 expert.</p> <p>19 Q. You're not an expert on warnings?</p> <p>20 A. Actually, I have been consulted on -- I've</p> <p>21 served on ACOG's Committee on Professional Liability;</p> <p>22 I was vice chair of that committee. I've also served</p> <p>23 on the ACOG's Quality and Patient Safety Committee</p> <p>24 and I'm presently on AUGS' Quality Committee.</p> <p>25 Q. Okay. What do those institutions -- what</p>
<p style="text-align: center;">Page 91</p> <p>1 TA in the histology class.</p> <p>2 Q. Where was that at?</p> <p>3 A. Loyola-Stritch in Chicago.</p> <p>4 Q. What book did you use?</p> <p>5 A. I don't even recall.</p> <p>6 Q. You're not an expert in polymer chemistry?</p> <p>7 A. No.</p> <p>8 Q. You've never done bench research on</p> <p>9 polypropylene?</p> <p>10 A. No, I have not.</p> <p>11 Q. Never done lab research on polypropylene?</p> <p>12 A. No.</p> <p>13 Q. Okay.</p> <p>14 A. I've implanted a lot of it, but I haven't</p> <p>15 done research on it.</p> <p>16 Q. Have you ever done any type of pathological</p> <p>17 analysis on explanted polypropylene mesh?</p> <p>18 A. Just on what I took out, looked at, and</p> <p>19 sent to the pathologist.</p> <p>20 Q. Okay. Have you ever looked under the</p> <p>21 microscope at explanted mesh?</p> <p>22 A. I can recall one time where I was with a</p> <p>23 pathologist, yes.</p> <p>24 Q. Okay. What was that?</p> <p>25 A. That was a revision of a TVT that had</p>	<p style="text-align: center;">Page 93</p> <p>1 do you do with warnings with those three groups?</p> <p>2 A. Actually, looking on the safety design for,</p> <p>3 say, obstetrical units and these kind of things.</p> <p>4 Q. Okay. What do you mean safety design? For</p> <p>5 the actual unit at the hospital?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. So you work with warnings for, like,</p> <p>8 beds in hallways?</p> <p>9 A. Well, what I do is looking at hospital</p> <p>10 design or team design for patient safety, is a better</p> <p>11 way to describe it.</p> <p>12 Q. You're not an expert on warnings related to</p> <p>13 medical devices, correct?</p> <p>14 A. No, I would not call myself an expert.</p> <p>15 Q. Okay. I mean, you don't know what risk</p> <p>16 information a medical device company needs to put</p> <p>17 inside an IFU, do you?</p> <p>18 MR. SNELL: Objection, form.</p> <p>19 THE WITNESS: I believe that the FDA</p> <p>20 has very specific guidelines.</p> <p>21 BY MR. KUNTZ:</p> <p>22 Q. Okay. You don't know what those are as we</p> <p>23 sit here today?</p> <p>24 A. No, I do not.</p> <p>25 Q. Okay. You've never looked at them, have</p>

Michael P. Woods, M.D.

Page 94	Page 96
<p>1 you?</p> <p>2 A. Not the guidelines from the FDA, no.</p> <p>3 Q. You've never drafted an IFU for a medical</p> <p>4 device?</p> <p>5 A. No.</p> <p>6 Q. You've never worked on warnings for a</p> <p>7 medical device?</p> <p>8 A. Not that I recall, no.</p> <p>9 Q. Okay. You have never worked on warnings</p> <p>10 for a prescription drug?</p> <p>11 A. No.</p> <p>12 Q. You're not a biomedical engineer?</p> <p>13 A. No, I am not.</p> <p>14 Q. You would agree you're not an expert on the</p> <p>15 design of medical devices?</p> <p>16 MR. SNELL: Form.</p> <p>17 THE WITNESS: I have worked on medical</p> <p>18 devices that have been patented, as a consultant.</p> <p>19 BY MR. KUNTZ:</p> <p>20 Q. Have you ever designed a medical device?</p> <p>21 A. Actually, I worked on the design of the</p> <p>22 LigaSure Extend clamp for vaginal hysterectomy.</p> <p>23 Q. Okay. Who manufactured that product?</p> <p>24 A. Valleylab.</p> <p>25 Q. What was your role in the design of that</p>	<p>1 must abide by?</p> <p>2 A. I know there are government standards. I</p> <p>3 do not know the exact ones.</p> <p>4 Q. But you don't know the names of them?</p> <p>5 A. No, I do not.</p> <p>6 Q. Okay. Did you use any of those standards</p> <p>7 when you were designing this device or consulting</p> <p>8 with Valleylab?</p> <p>9 A. I was more working with the engineers on</p> <p>10 that design.</p> <p>11 And as I say, I'm definitely not an expert</p> <p>12 on federal regulations. That's one of the things,</p> <p>13 when I was at ICON, I was trying to understand that</p> <p>14 complexity.</p> <p>15 Q. What are quality system regulations?</p> <p>16 A. Again, I -- you're beyond my scope.</p> <p>17 Q. What are current good manufacturing</p> <p>18 practice standards?</p> <p>19 A. I am -- I'm trying to think back on what I</p> <p>20 went through at ICON because we had a section on</p> <p>21 that, but I don't recall it.</p> <p>22 Q. Okay. When did you have this consulting</p> <p>23 agreement with Valley -- is it Valleylabs?</p> <p>24 A. Valleylab.</p> <p>25 I would have to look at when I did my</p>
<p style="text-align: center;">Page 95</p> <p>1 medical device?</p> <p>2 A. Looking at the length of the clamp and what</p> <p>3 I felt would be effective for deep pelvises. Also,</p> <p>4 they consulted me on the development of the LigaSure</p> <p>5 Precise, which was a small clamp for ENT.</p> <p>6 Q. Okay. Do you have a patent on medical</p> <p>7 devices?</p> <p>8 A. No, I do not.</p> <p>9 Q. When was this -- when was this device</p> <p>10 created?</p> <p>11 A. The LigaSure Extend?</p> <p>12 Q. Yes.</p> <p>13 A. I don't know the exact date. It's been on</p> <p>14 the market for quite a while. It had to be the early</p> <p>15 2000s.</p> <p>16 Q. Okay.</p> <p>17 A. It might -- might have been even the late</p> <p>18 1990s, but somewhere in that category. The Precise,</p> <p>19 I'm not sure when it came out.</p> <p>20 Q. What standards do manufacturers have to</p> <p>21 follow in designing medical devices?</p> <p>22 A. That it -- they state that what it does is</p> <p>23 actually what it does, but beyond that, I don't have</p> <p>24 a tremendous amount of knowledge.</p> <p>25 Q. Do you know what government standards they</p>	<p style="text-align: center;">Page 97</p> <p>1 study, and it was either late 1990s or early 2000s.</p> <p>2 Q. Okay. So you ran a study for them after</p> <p>3 the product was designed?</p> <p>4 A. No. I had done using another device that</p> <p>5 was shorter on a vaginal hysterectomy randomized</p> <p>6 study.</p> <p>7 Q. Do you know what a company research is</p> <p>8 before a product is designed or released?</p> <p>9 MR. SNELL: Form, vague, overbroad,</p> <p>10 incomplete hypothetical.</p> <p>11 BY MR. KUNTZ:</p> <p>12 Q. You can answer.</p> <p>13 A. I have vague ideas, but I -- I have no</p> <p>14 solid regulatory aspect at all.</p> <p>15 Q. Okay.</p> <p>16 A. I'm usually asked, you know, such as with</p> <p>17 my work with Ethicon is, "What is your opinion on</p> <p>18 this?" I worked on a couple of the other -- the</p> <p>19 other, like with TTV Secur, and then looking at some</p> <p>20 of the evolution ones, but as in the regulation, that</p> <p>21 is something that's not what I would -- I've got</p> <p>22 other things to be worried about.</p> <p>23 Q. You wouldn't consider yourself an expert in</p> <p>24 that area?</p> <p>25 A. Pardon me?</p>

Michael P. Woods, M.D.

Page 98	Page 100
<p>1 Q. You're not an expert in that area, correct?  2 MR. SNELL: Form, "that area."  3 THE WITNESS: I feel that I do not  4 have the knowledge base. I may have a very vague  5 knowledge base but not the level that would be  6 required in manufacturing.</p> <p>7 BY MR. KUNTZ:</p> <p>8 Q. Tell me how a medical device company goes  9 about designing a medical device.</p> <p>10 MR. SNELL: Objection: Form,  11 overbroad.</p> <p>12 THE WITNESS: I feel that in the  13 device they get an idea, and they do benchtop work,  14 and then it evolves through; and I would say I'm more  15 at the end of that process.</p> <p>16 BY MR. KUNTZ:</p> <p>17 Q. Okay. What experts are involved?  18 A. It would depend on what type of device.  19 Q. What about an SUI device?  20 A. I believe that with that you would have to  21 have your mechanical engineers, you would have to have  22 have your safety individuals, you would have to have  23 consulting with medical personnel, "Is this even a  24 real option to be looking at?"  25 Q. What's a design history file?</p>	<p>1 analysis?  2 A. I'm not sure.  3 Q. So safe to -- it's accurate to say you're  4 not sure what the purpose of a failure modes and  5 effects analysis is because you don't know what it  6 is?  7 A. Correct.  8 Q. Do you know -- do you recall, as you sit  9 here now, if you reviewed any of the failure modes  10 and effects analysis involved in this case?  11 A. If I did, it would have been very briefly.  12 Q. Do you know if warnings for a product are  13 part of the failure modes analysis?  14 A. If I don't know exactly what the failure  15 modes analysis is, I can't say that.  16 Q. Do you know what a DDSA is?  17 A. That name rings a bell. I'm trying --  18 Q. So you don't know, as we sit here right  19 now, or you don't recall?  20 A. Don't -- do not recall.  21 Q. What is ISO testing?  22 A. ISO testing is a standardized testing that  23 is used -- it's International Standards -- I want to  24 say Organization. I remember this some from my ICON  25 days.</p>
<p style="text-align: center;">Page 99</p> <p>1 A. I -- again, I -- I would suspect, by that  2 name, that it is the life -- the evolution of a  3 device.  4 Q. Okay. Did you review the design history  5 file for the TTV Retropubic?  6 A. I reviewed over -- I don't recall  7 specifically on that. When Ulmsten was first coming  8 out with this, with the integral theory, I found it  9 to be a real challenge to my dogma, for one, but in  10 looking at how he talked about using the various  11 suburethral components, I did look at that.  12 Q. Okay. Do you know, one way or another, if  13 you reviewed the design history file for the TTV, as  14 we sit here right now?  15 A. I did not. I do not have a bundle that  16 says that's what it is, no.  17 Q. Okay. Do you know what MedScan is?  18 A. I've heard of it. I'm not exactly -- I  19 believe that is -- I will say it would be pure  20 conjecture on --  21 Q. Do you know what Preventia is? Have you  22 ever heard of Preventia?  23 A. No. Actually, I might have heard -- the  24 name sounds, but...  25 Q. What's a failure modes and effects</p>	<p style="text-align: center;">Page 101</p> <p>1 And these are, I'm going to say,  2 international standards so that way if a study is  3 done in Croatia or the U.S., that they're using the  4 same base knowledge, I believe.  5 Q. Did you review any of the ISO testing that  6 was done on the TTV Retropubic?  7 MR. SNELL: Form, vague.  8 Go ahead.  9 THE WITNESS: If I did, it would have  10 been briefly.  11 BY MR. KUNTZ:  12 Q. Do you believe that the TTV mesh can rope?  13 A. I have not seen it in my own hands, and I'm  14 not aware in any Level 1 data that there's any  15 clinical indication of that.  16 Q. Okay.  17 A. I believe if you were to stretch it in --  18 beyond its physiologic meaning, yes.  19 Q. What is the physiological range for the  20 pelvic floor?  21 A. The -- 167 grams, I believe--I would have  22 to pull up a chart--is -- I would have to find that  23 chart. If I could look --  24 MR. KUNTZ: Yeah, let's take a quick  25 break.</p>

26 (Pages 98 to 101)

## Michael P. Woods, M.D.

Page 102	Page 104
<p>1 (11:34 a.m. to 11:48 a.m. - 2 Recess taken.)</p> <p>3 BY MR. KUNTZ: 4 Q. When we were off the record, you were 5 looking for a chart that discussed the physiological 6 forces of the pelvic floor; is that correct, Doctor? 7 A. This comes from a lecture--and this is one 8 of the ones from Gynecare at that time--where we 9 looked at pull-out force comparison. This was in a 10 human cadaver. The physiologic limit was 164 grams, 11 and then we looked at the pull-out force. 12 And in -- one of the things that I also did 13 in the TVT Abbrevo is I was one of the surgeons where 14 they compared the pull-out force of TVT Secur to TVT 15 Abbrevo and, actually, was there when they were doing 16 the measurements of pulling the sling out of the 17 tissues. And so when they talk about the physiologic 18 limit, this is the assumption within the pelvis. 19 Q. Okay. I'm going to mark that as, I 20 believe, Exhibit 3. 21 (Exhibit No. 3 marked for 22 identification.) 23 MR. SNELL: Thank you. 24 BY MR. KUNTZ: 25 Q. What is the date of this -- strike that.</p>	<p>1 Page 7, to a bar graph talking about the pull-out 2 forces of TVT-S and TVT, TVT-O? 3 A. Well, it was TVT Secur, both U and Hammock; 4 Retropubic TVT; and then TVT-O. 5 Q. Does this talk about the in vivo 6 physiological forces? 7 A. This was -- the 164 grams, I believe, was 8 in the pelvis, and then this was how well it stayed 9 in place at forces above that. 10 And so in this particular one, what we did 11 is we implanted the device, and then they hooked up 12 some machine that measured the force it took to 13 dislodge it out of the tissues. 14 Q. So this, we're talking about pull-out 15 forces as opposed to in vivo forces once the mesh is 16 left in the body, correct? 17 A. I believe -- 18 MR. SNELL: Objection: Form, asked 19 and answered. 20 Go ahead. 21 THE WITNESS: I believe this 164 is 22 the baseline -- 23 BY MR. KUNTZ: 24 Q. Okay. 25 A. -- the physiologic.</p>
<p>1 Is this your presentation? 2 A. This was -- any presentation I did when I 3 was speaking for Ethicon was approved by Ethicon. 4 Q. Okay. 5 A. I was allowed to have my own if it went 6 through legal review -- 7 THE REPORTER: "Have my own" -- 8 THE WITNESS: My own slides if it went 9 through legal review. 10 And so the only time that I would talk 11 about my own experience, or anything, is if I made 12 the qualifier, I'm now speaking not for Ethicon but 13 as a physician -- pelvic floor physician doing the 14 procedure. 15 BY MR. KUNTZ: 16 Q. So any presentation you gave for Ethicon 17 had to be approved by them? 18 A. If I was -- if I was speaking for them, 19 yes. 20 Q. Okay. Did you give this presentation for 21 them? 22 A. Yes. 23 Q. Okay. When was this given? 24 A. Multiple times. 25 Q. Okay. And you refer specifically, on</p>	<p>1 Q. Okay. And what's the basis for this study? 2 A. Specifically on this was looking at 3 pull-out forces and that it exceeded physiologic 4 forces. 5 Q. And where do we find that study, the 6 results of that study? 7 A. That would probably be in some of the 8 internal documents. 9 Q. Okay. Were those internal documents that 10 are part of your reliance list? 11 A. I do not recall that this was part of the 12 reliance list. 13 Q. Okay. Can you get us a copy of this study? 14 A. I think you would have to request it from 15 the company. I don't think I would have access to 16 it. 17 MR. KUNTZ: Can we get a copy to this 18 study, Burt? 19 MR. SNELL: Let me see. You mean the 20 actual cadaver study thing that they did? 21 MR. KUNTZ: Yes. 22 MR. SNELL: PSE 05-0396, Evaluation of 23 the Pullout Force. 24 We'll check. I would think -- that may -- 25 that's probably already been produced as part of</p>

Michael P. Woods, M.D.

Page 106	Page 108
<p>1 the -- you know, that PSE number does seem -- I have  2 seen that before. I think that has been produced.  3 BY MR. KUNTZ:  4 Q. When was this study done?  5 A. I do not know.  6 Q. Does this just relate to the force of the  7 mesh during implant?  8 A. It's the physiological limit of the mesh.  9 Q. During implant?  10 A. I believe so. I am not positive.  11 Q. Okay. Does this test the force of the mesh  12 when a patient is standing?  13 A. I -- I cannot say on that.  14 Q. Doctor, you were part of the study and  15 presented on it. Was it or was it not?  16 A. I was not a part specifically of this  17 study. I was a part of when TVT Abbrevio was coming  18 out. They utilized me as the TVT Secur expert and  19 then the placement of the TVT Abbrevio and then the  20 pull-out forces out of the tissue.  21 Q. Okay. So forces of the mesh on pull out  22 during the implant procedure, correct?  23 MR. SNELL: Objection, form.  24 THE WITNESS: No. This was where we  25 put enough tension on it that we actually</p>	<p>1 A. Correct, because it was a cadaver study.  2 And then I was involved in the development  3 of the TVT Abbrevio. It was will the device stay in  4 place; and, also, with Coloplast, I worked on a study  5 in the design of the anchoring mechanism for the  6 single-incision sling.  7 Q. Would you agree that the TVT was not  8 designed to rope?  9 A. I -- I would agree that when the TVT is  10 placed properly, I do not see any roping.  11 Q. Okay. Would you agree that when the TVT is  12 placed appropriately it doesn't -- it wasn't designed  13 to curl?  14 A. Curling would be a deformation, so that  15 should not occur when placing following instructions  16 for use.  17 Q. And when the TVT -- strike that.  18 Do you agree that the TVT was not designed  19 to fray?  20 A. Actually, the edges -- it depends what you  21 call fraying. I'm not sure -- when I hear fraying,  22 I'm not sure exactly what that means.  23 Q. What does fraying mean to you?  24 A. Fraying means to me that if you stretch it,  25 the edges start to change edges is what I would call</p>
<p style="text-align: center;">Page 107</p> <p>1 dislodged -- it was supraphysiologic to dislodge the  2 mesh to see if the anchoring was the same.  3 BY MR. KUNTZ:  4 Q. Did you play any role in the TVT pull-out  5 force study?  6 A. No.  7 Q. Okay. Have you ever seen the results of  8 that study?  9 A. I probably have. I just don't recall  10 specifically.  11 Q. Did it test the forces when the patient was  12 lifting something?  13 A. No, this was a cadaver study.  14 Q. So not -- so it's a cadaver study so it  15 couldn't be when the patient was lifting something,  16 correct?  17 A. Correct.  18 Q. It couldn't have been when the patient was  19 coughing, correct?  20 A. Correct.  21 Q. It couldn't have been when the patient was  22 sneezing, correct?  23 A. Correct.  24 Q. It couldn't have been when the patient is  25 running, correct?</p>	<p style="text-align: center;">Page 109</p> <p>1 fraying. There's other ways where you could sit back  2 and look at a mechanically cut edge and say, Well,  3 that edge is frayed because it's cut, it's not a  4 sealed edge.  5 I really -- I don't hold credence to  6 fraying. I don't honestly know what to think when  7 they say fraying.  8 Q. Have you ever talked to anybody else at  9 Ethicon about what they think the word fraying means?  10 A. I have talked to physicians that have said,  11 Well, along the edges there could be some fraying  12 because it's cut, and we cut mesh when -- if we are  13 doing a sacrocolpopexy, we cut the mesh using a  14 scissors to customize it, and they say, Well, the  15 edges could fray on that.  16 Q. Have you ever seen any internal documents  17 that suggest fraying of the mesh causes  18 complications?  19 A. I have looked at documents where they  20 talked about fraying and the potential, but I'm not  21 aware of any quality studies. That would be very  22 bottom-of-the-rung opinion. And when I was looking  23 at this, it was what are the randomized controlled  24 studies down to the cohort studies and these things.  25 But when it comes to opinion, that's expert opinion</p>

## Michael P. Woods, M.D.

Page 110	Page 112
<p>1 and that's -- the level of evidence that I looked at 2 was very low level.</p> <p>3 Q. Do you know if Ethicon has ever done a 4 study to see the difference in complications between 5 laser cut mesh and mechanical cut mesh?</p> <p>6 MR. SNELL: Objection: Form, 7 foundation.</p> <p>8 THE WITNESS: I believe that they have 9 not done a study; however, when we look at our 10 literature, so the laser cut mesh, which was utilized 11 more in Europe, if we were looking at the evolution 12 of studies that, say, start in 2008 to now, so they 13 are five years, seven years out, that we're not 14 showing an increased risk of complications or 15 differences. And so my feeling is that that has been 16 done just because we have studies that have followed 17 that long enough.</p> <p>18 MR. KUNTZ: And I'm going to move to 19 strike after studies have not been done.</p> <p>20 BY MR. KUNTZ:</p> <p>21 Q. And ask again, Doctor: Has there ever been 22 a study done by anybody comparing the complications 23 of laser cut mesh to mechanical cut mesh?</p> <p>24 MR. SNELL: Objection: Form, 25 foundation.</p>	<p>1 one of the meshes was used in post 2007? 2 A. You have those incorporated into the 3 studies that do not show any difference, so I have to 4 take --</p> <p>5 Q. But in any one of those studies does it say 6 whether laser cut mesh is used or mechanical cut mesh 7 is used?</p> <p>8 A. Not that I'm aware of --</p> <p>9 Q. Okay.</p> <p>10 A. -- for Retropubic TVT.</p> <p>11 Q. And you would agree that Ethicon still 12 sells both products?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. In any study -- and you can take as 15 long as you want. In all of your studies you have 16 post 2007, show me a study that distinguishes between 17 mechanical cut mesh and laser cut mesh.</p> <p>18 A. For Retropubic TVT?</p> <p>19 Q. Yes.</p> <p>20 A. Okay. Then what I would do is say that 21 that was not in the study design that I'm aware of.</p> <p>22 Q. Okay. Would you agree that the TVT mesh 23 was not designed to shrink?</p> <p>24 A. For Retropubic?</p> <p>25 Q. Yes.</p>
<p style="text-align: center;">Page 111</p> <p>1 THE WITNESS: What we do is we have to 2 take --</p> <p>3 BY MR. KUNTZ:</p> <p>4 Q. Doctor, answer the question: Yes or no?</p> <p>5 MR. SNELL: Same objection.</p> <p>6 BY MR. KUNTZ:</p> <p>7 Q. Have you ever -- as you sit here today, 8 have you ever seen a study comparing the difference 9 in complications between laser cut mesh and 10 mechanical cut mesh?</p> <p>11 A. Yes, because you have randomized controlled 12 studies that use both, follow the clinical 13 complications, and showed no difference.</p> <p>14 Q. Okay. Tell me what randomized clinical 15 trial you have anywhere in your materials that tracks 16 the difference between mechanical cut mesh and laser 17 cut mesh.</p> <p>18 A. It would be the assumption that if you have 19 data that -- you had implants or -- you --</p> <p>20 Q. Doctor, can you point to any study in all 21 of these studies you have that distinguishes that 22 mechanical cut mesh was used as opposed to laser cut 23 mesh post 2007?</p> <p>24 A. No.</p> <p>25 Q. Okay. Do any of these studies show which</p>	<p style="text-align: center;">Page 113</p> <p>1 A. There are studies that show that it does 2 not appear to shrink, yes.</p> <p>3 Q. Have you ever reviewed a study that shows 4 that the mesh in the TVT Retropubic shrinks?</p> <p>5 A. When you look at the Dietz study, it shows 6 that it does not.</p> <p>7 Q. That's not my question. Have you ever seen 8 a study in your thorough review in studies you've 9 been provided by defense counsel and studies you've 10 gone out and looked at on your own, ever seen a study 11 that says that the TVT mesh in the Retropubic 12 shrinks?</p> <p>13 A. I have not seen a quality study that 14 reflects that.</p> <p>15 Q. Okay. Have you seen any studies? In your 16 report you say you've never seen one. Do you 17 remember that?</p> <p>18 A. I -- I do not recall any studies -- I 19 recall studies that show it didn't. I don't recall 20 studies that show that it did.</p> <p>21 Q. Okay. So you've never been provided from 22 defense counsel any studies that show that the TVT 23 mesh shrinks?</p> <p>24 MR. SNELL: Objection: Form, 25 foundation.</p>

Michael P. Woods, M.D.

Page 114		Page 115	
1	THE WITNESS: TVT Retropubic?	1	A. That is correct.
2	BY MR. KUNTZ:	2	Q. I'm going to hand you what's been marked
3	Q. Yes.	3	Exhibit 5.
4	A. I do not recall.	4	(Exhibit No. 5 marked for
5	Q. Okay. Do you think that mesh in some of	5	identification.)
6	the other TTV devices shrinks? You keep saying --	6	MR. SNELL: Can I get a copy?
7	you keep clarifying "Retropubic." Is there a TTV	7	MR. KUNTZ: I'm sorry.
8	device where the mesh does shrink, in your mind?	8	MR. SNELL: No. 4 or 5, you said?
9	A. Not that I'm aware of.	9	MR. KUNTZ: 5.
10	Q. Okay. Have you ever seen any internal	10	MR. SNELL: 4 was prof. ed. slides?
11	documents from Ethicon that suggests that the Prolene	11	MR. KUNTZ: 4 was 2002.
12	mesh in the TTV Retropubic device shrinks?	12	MR. ROSENBLATT: 3 was the prof. ed.
13	A. No. And the literature would support that	13	slides.
14	we are not seeing the long-term complications that	14	MR. KUNTZ: 4 was the 2002 contract.
15	would be associated with it, such as increasing	15	MR. SNELL: Can I get a copy of that?
16	urinary retention. It tends to be stable over time.	16	MR. KUNTZ: It's not on the thumb
17	Q. What other -- are you aware of any -- well,	17	drive?
18	you don't believe it shrinks so you don't know what	18	MR. SNELL: I don't know.
19	complications it would cause, correct?	19	BY MR. KUNTZ:
20	MR. SNELL: Form, misstates.	20	Q. What is this document, Doctor?
21	BY MR. KUNTZ:	21	A. Could I ask a question? How do I update
22	Q. If the mesh did shrink, what complications	22	the CV to reflect 2002?
23	would it cause?	23	MR. SNELL: Don't worry about that.
24	A. If there -- and this is a hypothetical	24	THE WITNESS: Okay.
25	question, and so if -- what I would expect to see if	25	MR. SNELL: This is a deposition where
Page 115		Page 117	
1	there was shrinking would be increased outflow	1	you answer his questions to the best of your ability.
2	obstruction.	2	THE WITNESS: Okay.
3	Q. Okay. When did you first start consulting	3	MR. SNELL: You don't need to be
4	with Ethicon, Doctor?	4	worried about updating stuff.
5	A. I believe you reported that it was 2002.	5	BY MR. KUNTZ:
6	Q. And your CV says 2004, correct?	6	Q. I promise you at trial we will not
7	A. That is correct.	7	cross-examine you about your CV, about that.
8	Q. Are you going to go back and change that?	8	MR. SNELL: I hope you do.
9	A. If you -- I did not have all of my	9	So this is Exhibit 5.
10	documents on that. I would be glad to change the CV.	10	BY MR. KUNTZ:
11	Q. I'm going to hand you what's been marked	11	Q. Do you recognize that document?
12	Exhibit 4.	12	A. Yes.
13	(Exhibit No. 4 marked for	13	Q. And the maximum --
14	identification.)	14	A. I recognize my signature, anyway.
15	BY MR. KUNTZ:	15	Q. Right. That's your signature at the bottom
16	Q. Do you recognize that document?	16	of this.
17	A. My signature is on it, so yes.	17	A. Yes.
18	Q. And that's a consulting agreement that you	18	Q. And the maximum amount of this contract was
19	entered into in December of 2002, correct?	19	\$25,000, correct?
20	A. That is correct.	20	A. That's correct.
21	Q. And it's for the amount of \$50,000,	21	Q. Did you have a consulting agreement for
22	correct?	22	2004?
23	A. One moment here.	23	A. I believe so.
24	Q. The maximum amount of the contract was	24	Q. Okay. You can't find that one. Do you
25	\$50,000?	25	know what that amount was for?

Michael P. Woods, M.D.

<p>Page 118</p> <p>1 A. No idea. It was the maximum amount.  2 Whether I got paid that or not, I have no idea.</p> <p>3 Q. So some of these years you didn't get paid  4 the maximum amount; I assume that's your testimony?</p> <p>5 A. I would assume in some of those cases. In  6 most of the early years, I was actually working with  7 the Thermachoice device and not the uro/gyn device.</p> <p>8 Q. Do you keep track of how many payments you  9 received from Ethicon?</p> <p>10 A. I -- as I say, my office manager opened the  11 mail. I didn't have much contact with that at all.</p> <p>12 Q. Did you keep any of those records?</p> <p>13 A. Most of those have -- the oldest ones I --  14 wouldn't be there. I might have --</p> <p>15 Q. What years do you have?</p> <p>16 A. I don't know specifically with this. It  17 would be the accounting of the office. That was all  18 handled by my office manager.</p> <p>19 Q. Okay. Do you have any idea what years you  20 would have?</p> <p>21 A. No.</p> <p>22 Q. 2010?</p> <p>23 A. I would have to look and see. I -- we  24 should go back about seven years, I would say.</p> <p>25 Q. Okay. So you keep the records going back</p>	<p>Page 120</p> <p>1 yeah, it looks like it. It's a little bit poorly  2 copied, but yes.</p> <p>3 Q. And you'd agree the maximum amount  4 available on this contract was \$100,000?</p> <p>5 A. That's correct.</p> <p>6 Q. Did you have a consulting agreement for --  7 well, again, you've had one every year from 2002 --</p> <p>8 A. I believe so, yes.</p> <p>9 Q. -- up to 2013?</p> <p>10 I'm going to hand you what has been marked  11 as Exhibit 7.</p> <p>12 (Exhibit No. 7 marked for  13 identification.)</p> <p>14 BY MR. KUNTZ:</p> <p>15 Q. Is that your signature at the end?</p> <p>16 A. I'm looking for one. Yes.</p> <p>17 Q. And this maximum contract amount is 33,000,  18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. Let me hand you what's been marked  21 Exhibit 8.</p> <p>22 (Exhibit No. 8 marked for  23 identification.)</p> <p>24 THE WITNESS: Yes.</p> <p>25 MR. SNELL: Can I get a copy of that?</p>
<p>Page 119</p> <p>1 seven years?</p> <p>2 A. They're kept off-site, so -- and after  3 seven years, they're destroyed.</p> <p>4 Q. Okay. But you can get the ones for the  5 past seven years, correct?</p> <p>6 A. I'm not sure I would have the individual  7 receipts or just a summation; I'm not sure.</p> <p>8 Q. But, at the very least, you have a  9 summation?</p> <p>10 A. The accountant does, yes.</p> <p>11 Q. But you did have a consulting agreement for  12 2004?</p> <p>13 A. Yes, I believe I had a consistent  14 consulting up to date from, I guess, 2002 up to  15 whenever the last one was, which I'm unsure of.</p> <p>16 Q. Okay. You think it was two thousand -- the  17 end of 2013?</p> <p>18 A. That would be my best guess, but I'm...</p> <p>19 Q. Okay. I'm going to hand you what we've  20 marked as Exhibit 6.</p> <p>21 (Exhibit No. 6 marked for  22 identification.)</p> <p>23 BY MR. KUNTZ:</p> <p>24 Q. Is that your signature at the end?</p> <p>25 A. I'm flipping back to that. Yes -- well,</p>	<p>Page 121</p> <p>1 MR. KUNTZ: Uh-huh.</p> <p>2 MR. SNELL: Thank you.</p> <p>3 BY MR. KUNTZ:</p> <p>4 Q. Is that your signature?</p> <p>5 A. Yes, it is.</p> <p>6 Q. Okay. Is the maximum amount \$30,000 under  7 that contract?</p> <p>8 A. That is correct.</p> <p>9 Q. Okay. Do you know if you exceeded your  10 contract amount of \$30,000 in 2010?</p> <p>11 A. The answer is that all went to my office  12 manager. I pretty much didn't pay attention.</p> <p>13 Q. Okay. So you have no idea, as you sit here  14 today, any of the amounts you've been paid from  15 Ethicon?</p> <p>16 A. No, I don't. I really don't. They --</p> <p>17 Q. But you do keep summations of the last  18 seven years in storage?</p> <p>19 A. I -- I believe that they should be  20 available, yes.</p> <p>21 Q. Do you know if you signed a second contract  22 in 2010?</p> <p>23 A. I don't recall.</p> <p>24 Q. Okay. Would you disagree that you made  25 over \$135,000 from Ethicon in 2010?</p>

Michael P. Woods, M.D.

Page 122	Page 124
<p>1           MR. SNELL: Objection, foundation.</p> <p>2           THE WITNESS: I wouldn't disagree if</p> <p>3        you have the numbers.</p> <p>4    BY MR. KUNTZ:</p> <p>5    Q. And you signed a contract in 2011, correct?</p> <p>6    A. I believe so.</p> <p>7    Q. I'm going to hand you what is No. 9.</p> <p>8           (Exhibit No. 9 marked for</p> <p>9        identification.)</p> <p>10   BY MR. KUNTZ:</p> <p>11   Q. Is this a second contract for 2010?</p> <p>12   MR. SNELL: Objection: Form, lacks</p> <p>13   foundation.</p> <p>14   THE WITNESS: Yes. It says will cover</p> <p>15   11/23/2010.</p> <p>16   BY MR. KUNTZ:</p> <p>17   Q. Okay. And you signed this in 2010?</p> <p>18   A. I signed this -- I'm not sure if it's 11/19</p> <p>19   or 11/17/2010, yes.</p> <p>20   Q. What's the maximum amount on that contract?</p> <p>21   A. \$75,000.</p> <p>22   MR. SNELL: You're allowed to look at</p> <p>23   the document to answer his questions, okay?</p> <p>24   BY MR. KUNTZ:</p> <p>25   Q. Doctor, I'm going to go through several</p>	<p>1    BY MR. KUNTZ:</p> <p>2    Q. Did they pay for your travel expenses in</p> <p>3       all of these trips?</p> <p>4    A. They did pay for travel expenses, yes.</p> <p>5    Q. Did they pay for your time?</p> <p>6    A. They paid for my time, yes.</p> <p>7           Unfortunately, when I did these lectures or</p> <p>8        labs, I had a business to run, and in many times,</p> <p>9        actually, I lost money working and lecturing.</p> <p>10   Q. Okay. Do you know how many days in 2010</p> <p>11   you worked for Ethicon?</p> <p>12   A. There were some times where I would set</p> <p>13   aside two days a week, especially when we were doing</p> <p>14   the Thermachoice early on, where I would free that</p> <p>15   time up to go around the country, yes.</p> <p>16   Q. What year was that or years?</p> <p>17   A. Working with Thermachoice -- and that's</p> <p>18   probably more when it went back to 2002, because I</p> <p>19   worked extensively with Ethicon and national</p> <p>20   organizations on bringing that procedure into the</p> <p>21   office and then, also, worked on the economics of it,</p> <p>22   et cetera. It's -- it took a huge amount of energy.</p> <p>23   It was something I was very passionate about.</p> <p>24   Q. So some time period you spent two days a</p> <p>25   week consulting for Ethicon?</p>
<p style="text-align: center;">Page 123</p> <p>1    cities and tell me if you've attended an Ethicon</p> <p>2    event in that city.</p> <p>3       Denver?</p> <p>4    A. I -- yes.</p> <p>5    Q. Okay. Phoenix?</p> <p>6    A. Yes.</p> <p>7    Q. Chicago?</p> <p>8    A. Yes.</p> <p>9    Q. San Francisco?</p> <p>10   A. Yes.</p> <p>11   Q. Las Vegas?</p> <p>12   A. Yes.</p> <p>13   Q. Irvine, California?</p> <p>14   A. Yes.</p> <p>15   Q. St. Petersburg, Florida?</p> <p>16   A. Yes.</p> <p>17   Q. Sonoma, California?</p> <p>18   A. Yes.</p> <p>19   Q. Is that a wine dinner?</p> <p>20   A. I'm not sure if -- I'm -- I did an</p> <p>21   extensive amount of traveling for Ethicon. I</p> <p>22   wouldn't be able to tell you specific dates.</p> <p>23   Q. And that extensive amount of travel you've</p> <p>24   done has all been paid for by Ethicon, correct?</p> <p>25   MR. SNELL: Lacks foundation, form.</p>	<p style="text-align: center;">Page 125</p> <p>1    A. Probably in 2002 -- or somewhere '3, '5,</p> <p>2    somewhere in there; I would try to set aside two days</p> <p>3    a week, and then I opened my practice up on weekends</p> <p>4    and evenings when I was there in order to make up for</p> <p>5    the loss.</p> <p>6    Q. So two days a week during those time frames</p> <p>7    is over a hundred days a year?</p> <p>8    A. I wouldn't say -- on some weeks I would set</p> <p>9    aside two days. It would depend -- we had a huge</p> <p>10   coordinating effort. There was five of us nationwide</p> <p>11   that were doing a lot of the lectures on</p> <p>12   Thermachoice.</p> <p>13   Financially it was very difficult.</p> <p>14   Q. Same -- or Sonoma, California, you've been</p> <p>15   to?</p> <p>16   A. Yes.</p> <p>17   Q. Ethicon paid for that travel?</p> <p>18   A. Yes.</p> <p>19   Q. Salt Lake City?</p> <p>20   A. Yes.</p> <p>21   Q. Ethicon paid for that travel? "Yes"?</p> <p>22   A. Yes.</p> <p>23   Q. Dayton, Ohio?</p> <p>24   A. Yes.</p> <p>25   Q. Baltimore, Maryland?</p>

Michael P. Woods, M.D.

Page 126	Page 128
<p>1 A. Yes.</p> <p>2 Q. San Diego, California?</p> <p>3 A. Yes.</p> <p>4 Q. Orlando, Florida?</p> <p>5 A. If it's on that list, ab- -- you know.</p> <p>6 MR. SNELL: Just answer his questions, okay?</p> <p>7 THE WITNESS: I --</p> <p>8 MR. SNELL: Let me tell you. You're not here to assume things. You're here to answer his questions. That's it. Okay?</p> <p>9 THE WITNESS: Orlando I don't specifically recall, but I will say yes.</p> <p>10 BY MR. KUNTZ:</p> <p>11 Q. Dallas, Texas?</p> <p>12 A. Yes.</p> <p>13 Q. Kansas City?</p> <p>14 A. Yes.</p> <p>15 Q. Barcelona?</p> <p>16 A. I did lecture in Barcelona, yes.</p> <p>17 Q. Where else did you go in Europe for Thermachoice?</p> <p>18 A. Also London. I was brought in for an expert round table.</p> <p>19 Q. Do you know what cities you've been to</p>	<p>1 MR. SNELL: Same objection, to the extent you're using "promote." That's a running objection.</p> <p>2 THE WITNESS: I lectured --</p> <p>3 THE REPORTER: What was the last part on the objection?</p> <p>4 MR. SNELL: That's a running objection to the extent the word "promote" is in it.</p> <p>5 BY MR. KUNTZ:</p> <p>6 Q. Do you consider yourself out there promoting Ethicon products?</p> <p>7 A. I looked at it as I was educating physicians --</p> <p>8 Q. Okay.</p> <p>9 A. -- on the use of the device and, also, that if they were doing Retropubic slings, that this may be something that they could consider into their own armamentarium.</p> <p>10 Q. So you educated physicians about TVT Retropubic?</p> <p>11 A. Yes.</p> <p>12 Q. The TVT Obturator?</p> <p>13 A. Yes.</p> <p>14 Q. The Prosima?</p> <p>15 A. Yes.</p>
<p>1 specifically to promote pelvic floor products, SUI and POP?</p> <p>2 A. I didn't do as much -- much --</p> <p>3 MR. SNELL: Hold on, I'm sorry. I'm sorry. I missed -- I just saw the question.</p> <p>4 Objection, form.</p> <p>5 THE WITNESS: I don't -- I don't recall the exact cities. I did a lot of cadaver training. And exact lectures, I don't recall. I believe one that comes to mind was in southern California. I'm not sure what city.</p> <p>6 BY MR. KUNTZ:</p> <p>7 Q. Okay. And you were paid for all of these cadaver labs, correct?</p> <p>8 A. Correct.</p> <p>9 Q. Okay. And you were paid for all of these training courses?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And your expenses were paid?</p> <p>12 A. Yes.</p> <p>13 Q. You've promoted TVT Retropubic?</p> <p>14 A. Yes.</p> <p>15 MR. SNELL: Objection, form.</p> <p>16 BY MR. KUNTZ:</p> <p>17 Q. TVT-O?</p>	<p>1 Q. The Prolift+M?</p> <p>2 A. Yes.</p> <p>3 Q. The Prolift?</p> <p>4 A. Yes.</p> <p>5 Q. Thermachoice?</p> <p>6 A. Yes.</p> <p>7 Q. What other Ethicon products?</p> <p>8 A. TVT Secur.</p> <p>9 Q. Any other products from Ethicon or Johnson &amp; Johnson?</p> <p>10 A. No, not that I recall.</p> <p>11 Q. Did any of Ethicon's sales staff ever travel with you to any of these meetings?</p> <p>12 A. I -- they might be there, yes. And then --</p> <p>13 Q. So Ethicon would have sales reps at a lot of these meetings you attended?</p> <p>14 A. Yes.</p> <p>15 Q. Do you know Ethicon calls you one of their key surgeons; did you know that?</p> <p>16 A. I was aware of that, yes.</p> <p>17 Q. Would you agree you were a big advocate for Prosima?</p> <p>18 MR. SNELL: Form, foundation.</p> <p>19 THE WITNESS: I think I was a big advocate for pelvic floor reconstruction and the</p>

Michael P. Woods, M.D.

Page 130	Page 132
<p>1 treatment of incontinence, along with Thermachoice.  2 BY MR. KUNTZ:  3 Q. When you were out educating these surgeons  4 at these events, did you ever talk about any other  5 products besides Ethicon products?  6 A. Yes.  7 Q. Okay. What products would you talk about?  8 A. Well, when I would do -- especially with  9 Thermachoice, I had the other technologies available.  10 I, also -- with the Essure device, there was a couple  11 times where that was co-promoted.  12 Q. Did you work on the Essure device?  13 A. I actually was a consultant for them in  14 some of their Phase -- in the developing from Phase I  15 to II, yes.  16 Q. Is that still on the market?  17 A. Yes, it is.  18 Q. Do you think it's still within the standard  19 of care to place the TTV Secur?  20 A. It is now off the market, and if I had it  21 available in my hands, I had good results. The  22 unfortunate thing was that it was intersurgeon  23 variance, and that was one of the more frustrating  24 things I had with it is that it's a nuance procedure  25 and if you didn't understand the nuance, you didn't</p>	<p>1 products?  2 A. Yes, I have.  3 Q. You've been at company sales training  4 presentations?  5 A. Yes.  6 Q. You've been on advisory boards --  7 A. Yes.  8 Q. -- for Ethicon?  9 Have you ever told Ethicon you could not  10 work on one of their products?  11 A. I told Ethicon, if I had an ethical problem  12 with anything, I would not work on it.  13 Q. Okay. Has that ever occurred?  14 A. Not that I can recall.  15 Q. Have you ever told Ethicon that you felt  16 like one of its products was not safe?  17 A. No. I do not recall.  18 Q. Have you ever told Ethicon that they should  19 not market one of their products?  20 A. I do not recall.  21 Q. Do you disclose your relationship with  22 Ethicon to your patients prior to implanting the --  23 A. Yes.  24 Q. -- hold on, to implanting one of their  25 products?</p>
Page 131	Page 133
<p>1 get the good results.  2 Q. So you attended company-sponsored speaker  3 programs for Ethicon, correct?  4 A. Yes.  5 Q. You spoken at -- you spoken -- strike that.  6 Have you ever spoken for Ethicon in any  7 professional society meetings?  8 A. Yes, with the disclaimer that I was a  9 consultant with Ethicon.  10 Q. Which ones?  11 A. There's AAGL, I know. I'm sure there's  12 probably one of the annual clinical meetings at ACOG.  13 There's many -- there's more than that. I just don't  14 recall.  15 Q. Okay. And would Ethicon pay your travel to  16 attend these society meetings?  17 A. Sometimes they would. Sometimes, if I was  18 going to the society meeting, then I would pay my  19 own.  20 Q. Okay. Would you be in Ethicon's booth at  21 these society meetings?  22 A. I have been at Ethicon's booth in society  23 meetings. In fact, I did a live tele-surgery once.  24 Q. You've attended Ethicon or run  25 preceptorships and surgical training for their</p>	<p>1 A. Absolutely.  2 Q. Do you put that in your written consent?  3 A. No. I inform the patients that -- well,  4 not with Ethicon, but I actually tell them even  5 today, "I served as a consultant with this company.  6 I no longer have any financial ties." But I disclose  7 that to my patients on anything I recommend.  8 Q. Do you think inventors should be allowed to  9 participate in studies attempting to establish the  10 safety of the device or product they invented?  11 A. I believe that if they have done the  12 studies, are doing the studies with the idea that  13 they can be replicated, yes, but I would not have  14 much validity in somebody that does a study with  15 their device that has not been replicated by others.  16 I would not, in good conscience, be able to look at  17 that and tell the studies were done.  18 Q. You've read many studies that you reviewed  19 that the author state in the conflict of interest  20 section that they have some relationship with  21 Ethicon?  22 A. Yes.  23 Q. Okay. Have you ever asked to see their  24 consulting agreements?  25 A. No.</p>

Michael P. Woods, M.D.

<p style="text-align: right;">Page 134</p> <p>1 Q. Have you ever asked how much money any of 2 those physicians have been paid by Ethicon? 3 A. No. 4 Q. Have you reviewed any of the contracts 5 between Ulmsten and MedScan Ethicon related to his 6 purchasing agreement. 7 A. The only one that I recall was for a sum of 8 \$400,000 if the study -- multi-center study reflected 9 his data. That's the only one I recall. 10 Q. That's the only contract you've reviewed? 11 A. Would that be considered -- I guess it 12 would be considered a contract. 13 Q. But if you reviewed it, it's on your 14 reliance list? 15 A. Yes. 16 Q. Do you know AMS refers to you as a huge J&amp;J 17 supporter? 18 A. No. 19 Q. Does that surprise you? 20 A loyal customer; does that surprise you? 21 A. Wouldn't surprise me. 22 MR. SNELL: Objection -- objection, 23 foundation on "surprise." 24 BY MR. KUNTZ: 25 Q. Surprised that the AMS refers to you as a</p>	<p style="text-align: right;">Page 136</p> <p>1 more internal documents I'm not privy to. 2 Q. How many times have you visited Ethicon's 3 headquarters? 4 A. I'm unsure. 5 Q. Five? 6 A. More than five. 7 Q. 15? 8 A. Over the years, I would -- and I am just -- 9 this is a plain guess. 10 MR. SNELL: Well, you're not here to 11 guess, right? You're here to give testimony 12 truthfully under oath. You can give him -- what do 13 you call it, an estimate that's reasonable -- 14 MR. KUNTZ: Estimate. 15 MR. SNELL: -- but don't guess. He 16 doesn't want you to guess and I don't want you to 17 guess. Okay? 18 THE WITNESS: Honestly, I don't know. 19 More than ten. That's probably the best I could do. 20 I just have no idea. 21 BY MR. KUNTZ: 22 Q. All right. How many times have you visited 23 the AMS headquarters? 24 A. I believe three times. 25 Q. Okay. How many times have you visited</p>
<p style="text-align: right;">Page 135</p> <p>1 partner of Ethicon? 2 MR. SNELL: Same objection, relevance. 3 THE WITNESS: I guess what I would say 4 is AMS has approached me to be a consultant, so I'm 5 not aware -- I don't -- 6 BY MR. KUNTZ: 7 Q. Do you feel like you're a partner with 8 Ethicon or -- 9 A. Especially -- 10 Q. -- or were? 11 A. -- with Thermachoice, absolutely. 12 Q. What about with their SUI products? 13 A. I felt more as an educator. 14 Q. Would you agree at various times over the 15 past years you were Ethicon's highest volume user of 16 its products in the state of Nebraska? Do you know 17 that one way or another? 18 A. I do not know that, but it would not 19 surprise me. 20 Q. Do you know a single doctor in Nebraska 21 that's implanted more Ethicon products than you? 22 A. I haven't personally asked anyone, so I'm 23 not aware of anyone. 24 Q. What about in Iowa? 25 A. I haven't asked anyone. I -- that would be</p>	<p style="text-align: right;">Page 137</p> <p>1 Coloplast headquarters? 2 A. Probably four times. 3 Q. Where is AMS headquarters? 4 A. Both of them are in Minneapolis. 5 MR. KUNTZ: This might be a good 6 breaking point. 7 (12:29 p.m. to 1:31 p.m. - Recess 8 taken.) 9 BY MR. KUNTZ: 10 Q. Okay. We're back after lunch break, 11 Doctor. Is there anything you want to add to your 12 testimony from earlier this morning, or change? 13 A. I would like to clarify on when I would go 14 lecture for Johnson &amp; Johnson, that I was not paid 15 door to door. It would only be for the time that I 16 lectured, so if I spent a day getting someplace, I 17 was not compensated for that time. 18 Q. Thank you. 19 Anything else? 20 A. I -- 21 Q. Oh, I'm sorry. I had asked you before the 22 break to look through your report, to see if there 23 were any changes; you would look over at lunch. Why 24 don't you go ahead and tell me the correction or 25 addition you wanted to add.</p>

## Michael P. Woods, M.D.

Page 138	Page 140
<p>1        A. What page was that? I didn't take this 2 with me.</p> <p>3        Q. Let's go off the record.</p> <p>4                (Discussion off the record.)</p> <p>5        MR. KUNTZ: Okay. We're back on the 6 record now.</p> <p>7 BY MR. KUNTZ:</p> <p>8        Q. Doctor, you had a change in your report or 9 just an editorial error, I guess, or addition. Will 10 you tell us what you changed.</p> <p>11        A. What the sentence had stated priorly was 12 (Reading):</p> <p>13                By contrast, surgeons performing autologous 14 fascial slings would utilize a 1 centimeter tube 15 knitted Dacron buttress with a Stamey procedure with 16 a 1 centimeter tube of knitted Dacron arteriography 17 to help prevent the suture from tearing through the 18 tissues.</p> <p>19                My correction is:</p> <p>20                By contrast, surgeons performing Stamey 21 procedure would utilize a 1 centimeter tube of 22 knitted Dacron arteriography to keep -- to help 23 prevent the suture from tearing through the tissues.</p> <p>24        Q. Thanks.</p> <p>25        Can you tell me a little bit about your</p>	<p>1        last five years.</p> <p>2        Q. How many laparoscopic Burches did you 3 perform in your career?</p> <p>4        A. I would say 50 to 100 as an estimate.</p> <p>5        Q. And you were doing those in the early '90s?</p> <p>6        A. The laparoscopic Burches were more in the 7 later '90s.</p> <p>8        Q. You agree, when you stated in your report, 9 that the success rate with Burch is 70 to 80 percent, 10 correct?</p> <p>11        A. I'm -- in my report, I do state in there, 12 but, also, in longitudinal studies it has been shown 13 to decrease over time.</p> <p>14        Q. What's the success rate for the TVT?</p> <p>15        A. It would depend on how you determine 16 success.</p> <p>17        Q. Okay. What about for recurrence? I'm 18 sorry. What about for incontinence? I mean --</p> <p>19        A. The goal with success would be, from my 20 perspective, patient satisfaction, is your life 21 improved.</p> <p>22        When I look at the literature, what I want 23 to look at is does it last long term, are the 24 complications acceptable. We are now doing -- asking 25 validated questionnaires of patients, which is</p>
<p style="text-align: center;">Page 139</p> <p>1        current practice, what you do week to week.</p> <p>2        A. My current practice is I am a 3 urogynecologist at Shenandoah Medical Center. I also 4 do some general gynecology. I would say about 5 85 percent of what I do is urogynecology, 15 percent 6 gynecology; however, when my partner is out of town, 7 I will take call for obstetrics.</p> <p>8        Q. Okay. What type of surgeries do you 9 perform?</p> <p>10        A. I perform native tissue vaginal repairs, I 11 perform various types of sling procedures, I perform 12 laparoscopy, though my special interest is vaginal 13 surgery, and I also do perform blocks for pelvic 14 pain.</p> <p>15        Q. Okay. Do you perform pubovaginal slings?</p> <p>16        A. I have performed one in the last five 17 years.</p> <p>18        Q. What were those circumstances?</p> <p>19        A. It was in a patient that did not want to 20 have mesh implanted.</p> <p>21        Q. Ever perform a Burch procedure? Strike 22 that.</p> <p>23        When is the last time you performed the 24 Burch procedure?</p> <p>25        A. I do not recall performing a Burch in the</p>	<p style="text-align: center;">Page 141</p> <p>1        something that I'm just starting to do. Also, 2 assessing is the quality of life or when I see them 3 for their immediate post-op check, which is usually 4 at about four weeks, I'm assessing: Is the tissue 5 healed, is it tender, are they happy with the 6 results, making sure that they're not in retention, 7 and I always ask them, "Is your life better?"</p> <p>8        Q. Okay. And what -- from a patient 9 satisfaction standpoint, what is the success rate for 10 TVT?</p> <p>11        A. In my own hands, it's probably about 95, 12 96 percent.</p> <p>13        Q. What about in the literature?</p> <p>14        A. The literature is variable but in the upper 15 80s to low 90s.</p> <p>16        Q. Have you seen studies that put it below?</p> <p>17        A. Yes, there are studies out there, but when 18 you look at the randomized controlled studies or the 19 meta-analysis or such Cochrane reviews or such as the 20 SGS, they're in the 80 range.</p> <p>21        Q. Do you use any synthetic mesh for prolapse 22 repair?</p> <p>23        A. I do for sacrocolpopexy, and recently I did 24 have a patient that I used a vaginal approach, that I 25 cut because there was a very large defect on one side</p>

Michael P. Woods, M.D.

<p style="text-align: right;">Page 142</p> <p>1 so I hand cut the mesh for a paravaginal repair.    2 Q. Aside from that one patient, you don't use    3 synthetic mesh transvaginally to perform organ    4 prolapse repairs, correct?    5 A. I do not feel that I have done enough    6 lately, and because I was what I would call an expert    7 on Prolift and is no longer on the market, I have    8 waited to see with the other kits, but I have not --    9 I do not feel that I have enough adequate training at    10 this point to proceed with implanting them, because    11 I'm not trained specifically on that implant device.    12 And I feel very strongly that you -- physicians, if    13 they're going to be implanting, need to be trained    14 specifically on the nuances of that device.    15 Q. Do you treat patients for complications    16 related to slings?    17 A. Yes.    18 Q. Okay. Do you treat patients for    19 complications related to the TTVT Retropubic?    20 A. Yes.    21 Q. What are the type of complications you    22 treat for TTVT Retropubic?    23 A. It would be mesh erosions into the vagina    24 and urinary retention would be the big two that I    25 would see, and that's still in a minority of</p>	<p style="text-align: right;">Page 144</p> <p>1 A. Yes.    2 Q. Okay. How many?    3 A. I would say my reoperation rate is right    4 around 3 percent, so --    5 Q. Is that for your own patients?    6 A. Yes.    7 Q. Okay. What about --    8 A. 2 to 3 percent, yes.    9 Q. How many revisions have you done on    10 patients that weren't your own patients?    11 A. I would be taking a guess. Over the last,    12 say, ten years or so, around 100. That wouldn't just    13 be TTVT, though. That would be any suburethral mesh,    14 whether it was TTVT or Sparc. I -- I don't really    15 break that all down.    16 Q. So for your -- I want to make sure this is    17 clear. For your patients, with the TTVT Retropubic is    18 a 3 percent reoperation rate?    19 A. Yes, I would say.    20 Q. And in total, all midurethral slings    21 combined you've performed approximately 100 revision    22 surgeries; is that accurate?    23 A. That -- I think we would have to go back    24 and read the question, again, because I think it was    25 referred -- or patients that I did not operate on.</p>
<p style="text-align: right;">Page 143</p> <p>1 patients.    2 Q. What about chronic pain?    3 A. With chronic pain, what I do is I evaluate    4 very certain areas --    5 Q. And hold on, before you explain it, do you    6 treat patients for chronic pain related to the TTVT    7 Retropubic device?    8 A. I have treated one patient and in all of my    9 time directly related to TTVT.    10 Q. Was that your own patient?    11 A. No, it was not. That was actually referred    12 in by the urologist that performed it.    13 Q. Okay. What about dyspareunia.    14 A. I really don't see dyspareunia with this.    15 I see lots of patients with dyspareunia, but when I    16 have a patient that has had a Retropubic sling,    17 whether I placed it or anybody else, what I do is I    18 try to elicit exactly the dyspareunia. So in the    19 history, is it on deep penetration, is it on    20 penetration, where is it located; and then I actually    21 map out in the pelvis where the pain is located.    22 Q. Have you ever done any revisions on TTVT    23 Retropubic --    24 A. Yes.    25 Q. -- products?</p>	<p style="text-align: right;">Page 145</p> <p>1 Can you --    2 Q. Okay. Let me see if I can clean this up.    3 How many -- approximately how many revision surgeries    4 have you done on slings of any type, in total?    5 A. I would say -- because lately I haven't    6 been seeing that many, anywhere between five and ten    7 a year I believe would be a reasonable estimate.    8 Q. Okay. Since two --    9 A. I'm just going to say, the last ten years.    10 Q. Now, your reoperation rate for just TTVT    11 Retropubic is 3 percent?    12 A. 2 to 3 percent. I would -- usually that    13 would either be a mesh erosion -- I presented a    14 abstract on the treatment of mesh erosions with    15 laser. I don't remember the breakdown of the    16 patients on that.    17 Q. So did you --    18 A. Or ureterolysis, so simple procedures.    19 Q. Did you -- and I think you told me you put    20 in approximately 2,000 Retropubic slings?    21 A. Somewhere in there.    22 Q. And that was Retropubic slings?    23 A. Well, I would modify that and say    24 2,000-plus slings, yes.    25 Q. The whole universe of slings?</p>

Michael P. Woods, M.D.

Page 146	Page 148
<p>1       A. Right.</p> <p>2       Q. You don't keep track of that number?</p> <p>3       A. Not --</p> <p>4            MR. SNELL: Objection, form.</p> <p>5            THE WITNESS: -- anymore.</p> <p>6    BY MR. KUNTZ:</p> <p>7       Q. Okay. How did you come up with your reoperation rate being 3 percent?</p> <p>8            MR. SNELL: Objection, misstates. He said 2 to 3 percent.</p> <p>9    BY MR. KUNTZ:</p> <p>10       Q. Okay. How did you come up with your reoperation rate being 2 to 3 percent?</p> <p>11       A. When I would have a patient come on back and they would either have a voiding dysfunction or urethral -- or not a urethral, a vaginal erosion--I haven't had a urethral erosion yet--then I would sit back and have a good guesstimate of how many I done because I do them very often.</p> <p>12       And then I would sit back and say this would be -- this is how many I've done this year, this is how many I've implanted this year.</p> <p>13       Q. Okay. And so did you keep track of how many you implanted each year?</p> <p>14       A. I kept a running track in my mind.</p>	<p>1       the type of operations you do, correct?</p> <p>2            MR. SNELL: Objection, misstates.</p> <p>3            THE WITNESS: Correct.</p> <p>4            MR. SNELL: Did you say types?</p> <p>5            MR. KUNTZ: Yeah.</p> <p>6            MR. SNELL: That's a misstatement. Object, form.</p> <p>7    BY MR. KUNTZ:</p> <p>8       Q. Do you keep numbers anywhere besides your head of any operations you do?</p> <p>9            A. Yes.</p> <p>10       Q. Where?</p> <p>11       A. They would be in billing records and things, but I don't have those available to me.</p> <p>12       Q. Can you get those?</p> <p>13       A. I do not know if I can get those.</p> <p>14       Q. Okay. And when you looked and you put numbers in your expert report of 1 percent erosion rate, 2 to 3 reoperation rate, that's all coming from your head, correct?</p> <p>15       A. My data closely reflects the data that's out there, yes.</p> <p>16       Q. That wasn't my question. All of those numbers in your report came from your mental estimates as opposed to looking at any hard data or</p>
<p style="text-align: center;">Page 147</p> <p>1       Q. So this is a mental list?</p> <p>2       A. Yes.</p> <p>3       Q. So you don't have any list anywhere where you have exact numbers written down on a spreadsheet or piece of paper --</p> <p>4       A. No.</p> <p>5       Q. -- for the amount you've implanted?</p> <p>6       A. No.</p> <p>7       Q. Okay. For the amount you've done reoperations on?</p> <p>8       A. No.</p> <p>9       Q. Okay.</p> <p>10       A. I mean, there would probably be some billing records, or something, somewhere where we could look, but...</p> <p>11       Q. So you could maybe find that number if you looked for it?</p> <p>12       A. Actually, I'm no longer using that billing service and so I'm not sure I could find it using the billing.</p> <p>13       Q. And does that go for your erosion rate, too; that's a guesstimate, that's not something you keep hard numbers on?</p> <p>14       A. No, I don't keep hard numbers on.</p> <p>15       Q. Okay. So you don't keep hard numbers on</p>	<p style="text-align: center;">Page 149</p> <p>1       numbers to make those determinations; is that accurate?</p> <p>2            A. I would say that that is reasonably accurate.</p> <p>3       Q. Have you ever removed or revised mesh because of pain?</p> <p>4            A. I talked about the one earlier where this was a urologist that sent a patient in that had an ilioinguinal nerve pain that responded to a block. And then I excised that part above the fascia.</p> <p>5       Q. Do you believe TTVT Exact is the gold standard?</p> <p>6            A. I do not believe that the randomized control studies are going to suggest a gold standard for anything but Retropubic, whether it's TTVT or TTVT Exact.</p> <p>7       Q. Okay. Do you think the mechanical cut mesh is the gold standard or the laser cut mesh?</p> <p>8            A. I believe that the data shows in the long term that mechanical cut was the gold standard. But the change, and as we've talked about earlier, is do the studies delineate whether it's laser cut or mechanically cut, and that I -- that I cannot expound upon.</p> <p>9       Q. Is the AMS MiniArc the gold standard?</p>

Michael P. Woods, M.D.

<p style="text-align: right;">Page 150</p> <p>1        A. I feel that the AMS MiniArc is an 2 alternative, but it is not -- long-term studies are 3 not there, so I cannot assess that.</p> <p>4        Q. What about the TTV Abbrevio; is that the 5 gold standard?</p> <p>6        A. Again, the -- when I have to look at what I 7 was asked to do evaluating Retropubic TTV and, 8 specifically, mechanically cut, the data on that and 9 in some of the authors have said that it is the gold 10 standard.</p> <p>11      Q. Have you ever done a survey of any 12 physicians to determine what they believe is the gold 13 standard --</p> <p>14      A. No, I have not.</p> <p>15      Q. -- yourself?</p> <p>16      Do you believe that the AUGS physician 17 statement applies to all slings across the board?</p> <p>18      A. I think that when AUGS and SUFU came 19 together, they reviewed the meta-analysis data and 20 that applied most of the RCTs, the higher Level 1s, 21 are Retropubic TTV.</p> <p>22      Q. Do you agree that the AUGS statement says 23 that the data is only good for up to one year?</p> <p>24      A. They were -- let me have the AUGS statement 25 so I can make sure I'm not misquoting, please. This</p>	<p style="text-align: right;">Page 152</p> <p>1        Q. Do you agree or disagree with that 2 statement?</p> <p>3        A. That that is in this document, but that is 4 just one part of the document.</p> <p>5        Q. Do you agree with that statement or 6 disagree with that statement?</p> <p>7        A. That was the FDA statement. That wasn't 8 the AUGS statement. It was included in the AUGS 9 part.</p> <p>10      Q. Why was it included in the AUGS statement?</p> <p>11      A. Because when they were doing this, they 12 had -- this was one part and this is -- they wanted 13 to include that the FDA had looked at that.</p> <p>14      Q. Okay. So do you agree or disagree with 15 that statement by the FDA?</p> <p>16      A. I -- on the FDA website, I agree that the 17 FDA felt that the safety and effectiveness of 18 multi-incision slings is well established; however, 19 there are RCTs and other studies that go up to 17 20 years, but the FDA, specifically at that meeting, 21 said the one-year data.</p> <p>22      Q. Is the Nilsson/Ulmsten study an RCT?</p> <p>23      A. No, it is not.</p> <p>24      Q. Okay. Which one goes up to 17 years?</p> <p>25      A. I --</p>
<p style="text-align: right;">Page 151</p> <p>1        may take me a second, too.</p> <p>2        MR. SNELL: That's fine.</p> <p>3        Do you have a copy of it handy?</p> <p>4        MR. KUNTZ: No, I don't, no. I 5 thought you kept one in your briefcase.</p> <p>6        MR. SNELL: There are so many good 7 position statements.</p> <p>8        (Discussion off the record.)</p> <p>9        THE WITNESS: I thought I had it in 10 this pile.</p> <p>11      BY MR. KUNTZ:</p> <p>12      Q. I thought I saw it in there, too. We can 13 get a copy of it.</p> <p>14      A. AUGS Position Statement on Mesh Midurethral 15 Slings for Stress Incontinence -- is this the one?</p> <p>16      And what did you want --</p> <p>17      Q. Let me see this.</p> <p>18      A. -- because there's a lot to...</p> <p>19      Q. Do you agree with this statement, Doctor:</p> <p>20      That the safety and effectiveness of multi-incision 21 slings is well established in clinical trials that 22 follow patients for up to one year?</p> <p>23      A. That's one part of the document.</p> <p>24      Q. Uh-huh.</p> <p>25      A. How --</p>	<p style="text-align: right;">Page 153</p> <p>1        Q. Which RCT goes up to 17 years?</p> <p>2        A. There are no RCTs that go to 17 years.</p> <p>3        Q. How many long-term RCTs are there that 4 study the TTV Retropubic device? Back up. What do 5 you consider a long-term RCT?</p> <p>6        A. I consider a long-term study at least three 7 years by the International Incontinence Society's 8 recommendations.</p> <p>9        Q. There's not one for 17 years, as you just 10 said, is there?</p> <p>11      A. No.</p> <p>12      Q. Okay. Let's go with this. Do you agree 13 with that statement or not, Doctor?</p> <p>14      MR. SNELL: Objection: Asked and 15 answered.</p> <p>16      THE WITNESS: I agree that this was on 17 the FDA website. I feel that there is other data 18 that looks at longer-term data than one year.</p> <p>19      BY MR. KUNTZ:</p> <p>20      Q. So you disagree with that statement?</p> <p>21      MR. SNELL: Objection, asked and 22 answered.</p> <p>23      THE WITNESS: I believe it's well 24 established for one year and beyond, yes.</p>

Michael P. Woods, M.D.

<p style="text-align: center;">Page 154</p> <p>1 BY MR. KUNTZ:</p> <p>2 Q. How many TTV Retropubic devices have been 3 implanted?</p> <p>4 A. Between 700,000 and a million worldwide.</p> <p>5 Q. Okay. So no more than a million, right?</p> <p>6 A. I would have to give a guess. I'm not --</p> <p>7 Q. Where did you come up with 700,000?</p> <p>8 A. I believe that there was a -- let me look 9 through my position statement here. This may take me 10 a second.</p> <p>11 I'm going to pull this from Page 17 and 12 this goes back to 2002. As of 2002, there were 13 200,000 TTV procedures performed with reference to 14 Debodinance. As of 2006, there were over 700,000 TTV 15 procedures performed worldwide, and that's Lord 2006.</p> <p>16 Those will be two of the -- that's where I 17 came up with the 700,000 number.</p> <p>18 Q. Okay. Do you agree that the AUGS statement 19 applies to all midurethral slings and not just the 20 TTV Retropubic device?</p> <p>21 A. No. Actually, it does not apply to the 22 single-incision slings.</p> <p>23 Q. Does it apply to TTV Abbrevio?</p> <p>24 A. I think this was their position statement 25 on midurethral slings in general. I'm looking to see</p>	<p style="text-align: center;">Page 156</p> <p>1 to the spacing device.</p> <p>2 Q. Do you tension it loosely?</p> <p>3 A. I bring it to where it's just in contact so 4 it will be loose.</p> <p>5 Q. Okay. So you tension it loosely?</p> <p>6 A. Yes.</p> <p>7 Q. Do you believe that the TTV device is 8 tension-free?</p> <p>9 A. I believe that when it is placed is about 10 as tension-free as you can get underneath the 11 urethra, because there's actually a space between the 12 urethra and the mesh.</p> <p>13 Q. Do you agree that the strongest unmet need 14 with the TTV is the ability to adjust tension both 15 intraoperatively and postoperatively?</p> <p>16 MR. SNELL: Form.</p> <p>17 THE WITNESS: Could you -- could 18 you -- could you repeat that question for me, please.</p> <p>19 BY MR. KUNTZ:</p> <p>20 Q. Do you agree that the strongest unmet -- 21 strike that.</p> <p>22 You talk to physicians about TTV Retropubic 23 all of the time, don't you?</p> <p>24 A. Yes.</p> <p>25 Q. Have any of them ever told you their</p>
<p style="text-align: center;">Page 155</p> <p>1 if they talked about the FDA and the single-incision 2 slings.</p> <p>3 The only reference to that is they put -- 4 in this document is explicitly stated: The FDA 5 continues to evaluate the effects of using surgical 6 mesh for the treatment of SUI and will report about 7 that usage at a later date.</p> <p>8 So they did not -- with this, they just -- 9 this was a blanket on midurethral slings.</p> <p>10 Q. What's the proper way to tension the TTV 11 Retropubic device?</p> <p>12 A. The TTV Retropubic device, after you pass 13 the trocars through, you place a spacing device, when 14 you are doing the adjusting, and you place a spacing 15 device between the urethra and the mesh material. 16 Once you cut these off, you then can have a patient 17 cough with that device out to make sure, if they're 18 awake, do they leak a couple of drops. And then the 19 device is put back in and you pull the sheaths off.</p> <p>20 Q. How do they cough under general anesthesia?</p> <p>21 A. Under general anesthesia, you can do a 22 Credé maneuver.</p> <p>23 Q. Do you use minimal tension on the TTV 24 Retropubic device?</p> <p>25 A. What I do personally is I bring the mesh up</p>	<p style="text-align: center;">Page 157</p> <p>1 concerns about -- with the ability to adjust tension 2 both intraoperatively and postoperatively; have you 3 ever heard that?</p> <p>4 A. I have heard the postoperatively. 5 Intraoperatively I have not had.</p> <p>6 Q. Okay.</p> <p>7 A. That's new to me.</p> <p>8 Q. Have you ever heard that that's one of the 9 strongest unmet needs of the TTV device?</p> <p>10 A. I -- I can't honestly say that I feel it's 11 been an unmet need.</p> <p>12 Q. Okay. Do you agree that the mesh in the 13 TTV may be too wide?</p> <p>14 A. I believe that it -- that it is studied and 15 I have to go by the -- that level of evidence which 16 is the same width.</p> <p>17 Q. Okay. Do you believe that there's a risk 18 the TTV mesh will fold on itself, roll up on a 19 patient and cause discomfort?</p> <p>20 MR. SNELL: Form.</p> <p>21 THE WITNESS: I believe when it is 22 properly placed, that it will not.</p> <p>23 BY MR. KUNTZ:</p> <p>24 Q. You've never seen anything to the contrary 25 when it's properly placed?</p>

## Michael P. Woods, M.D.

Page 158	Page 160
<p>1       A. Not in my own personal experience.</p> <p>2       Q. Okay. What about in the literature?</p> <p>3       A. I had heard on an explanted that there may</p> <p>4       have been a folding, or something, yes.</p> <p>5       Q. Where did you hear that?</p> <p>6       A. That -- actually, that wasn't in the</p> <p>7       literature. That was a physician that when they had</p> <p>8       excised it felt that it was folded on itself.</p> <p>9       Q. What physician? Who was that that you</p> <p>10      discussed that with, do you know?</p> <p>11      A. It was at a meeting. I don't recall who.</p> <p>12      Q. Do you agree there's no calibration to let</p> <p>13      you know when you have the TTV tensioned right?</p> <p>14        MR. SNELL: Form, objection.</p> <p>15        THE WITNESS: I believe that what we</p> <p>16       do is we do a test, either with Credé maneuver or</p> <p>17       having the patient cough, to see if there's a little</p> <p>18       bit of leakage of urine.</p> <p>19        BY MR. KUNTZ:</p> <p>20        Q. Okay.</p> <p>21        A. But as in putting a device to measure</p> <p>22       tensioning, no.</p> <p>23        Q. Okay. Have you ever heard that there is no</p> <p>24       consensus on the amount of tension needed and many</p> <p>25       feel the tension will vary based on the patient's</p>	<p>1        MR. SNELL: Form.</p> <p>2        THE WITNESS: I would ask them to show</p> <p>3       me the study that was randomized to prove that.</p> <p>4        BY MR. KUNTZ:</p> <p>5        Q. Would you disagree with the physician if he</p> <p>6       had said that he had to laser cut mesh slings in much</p> <p>7       tighter than the mechanically cut ones?</p> <p>8        MR. SNELL: Form.</p> <p>9        THE WITNESS: I am not that physician.</p> <p>10      I wouldn't be able to say.</p> <p>11        BY MR. KUNTZ:</p> <p>12        Q. Okay. Would you disagree with that</p> <p>13       physician?</p> <p>14        MR. SNELL: Form.</p> <p>15        THE WITNESS: In my own personal</p> <p>16       experience, yes.</p> <p>17        BY MR. KUNTZ:</p> <p>18        Q. Okay. All of these studies that you</p> <p>19       reviewed, did you ever do an analysis of the studies</p> <p>20       that actually tracked long-term pain over six months?</p> <p>21        A. What I did on the RCTs is I looked at the</p> <p>22       pain parts to it and also looked at the AUA</p> <p>23       information on pain in those patients.</p> <p>24        Q. Okay. How many studies tracked pain over</p> <p>25       six months?</p>
<p style="text-align: center;">Page 159</p> <p>1        presentation and patient anatomy?</p> <p>2        MR. SNELL: Form.</p> <p>3        THE WITNESS: I believe that if you</p> <p>4       have a spacing device, no matter what the anatomy, it</p> <p>5       is not in contact with the urethra and the placement.</p> <p>6        BY MR. KUNTZ:</p> <p>7        Q. Do you agree that there is some guesswork</p> <p>8       in adjusting the tension of the TTV Retropubic</p> <p>9       device?</p> <p>10        MR. SNELL: Form.</p> <p>11        THE WITNESS: Actually, no, I don't.</p> <p>12       Of all the procedures I've done it is probably the</p> <p>13       easiest to tension.</p> <p>14        BY MR. KUNTZ:</p> <p>15        Q. Do you think the tensioning is the same</p> <p>16       with both the mechanical cut mesh and the laser cut</p> <p>17       mesh?</p> <p>18        A. I use the same spacing device in both --</p> <p>19        Q. Okay.</p> <p>20        A. -- for Retropubic.</p> <p>21        Q. So is that a "Yes"?</p> <p>22        A. Yes.</p> <p>23        Q. If someone said that the laser cut mesh</p> <p>24       needed to be tensioned more loosely under the</p> <p>25       urethra, would you disagree with them?</p>	<p style="text-align: center;">Page 161</p> <p>1        A. There would be several that would include</p> <p>2       that in their complication rates. I'm going to look</p> <p>3       for the American Urology Association's paper that we</p> <p>4       had earlier. And this has been revised. This is</p> <p>5       2009, but it's been revised.</p> <p>6        And when they looked at their literature,</p> <p>7       they followed pain. In nine -- if you want, I can</p> <p>8       kind of go through --</p> <p>9        Q. Sure.</p> <p>10       A. -- each of these. In all Retropubic</p> <p>11       suspensions, pain 6 percent, sexual dysfunction</p> <p>12       7 percent, voiding dysfunction 16 percent. So I'm</p> <p>13       going to exclude those. We don't have a breakdown on</p> <p>14       dyspareunia here or pain with intercourse, but the</p> <p>15       sexual dysfunction in Burch colposuspension, pain of</p> <p>16       9 percent, sexual dysfunction of 7 percent, and then</p> <p>17       voiding dysfunction, again, 16 percent.</p> <p>18       Q. And how long do they track the pain?</p> <p>19       A. I would have to pull up their -- I don't</p> <p>20       have the whole sheet here. I would have to pull up</p> <p>21       their list.</p> <p>22       Q. In all of this literature review, did you</p> <p>23       ever do your own analysis to see how many of these</p> <p>24       studies that you talked about decided to track pain</p> <p>25       over six months?</p>

Michael P. Woods, M.D.

<p>1 A. They followed the pain and they reported 2 that.</p> <p>3 Q. You're not -- you're not following me. Did 4 you ever look at all of these studies and do your own 5 analysis to see how many of them tracked pain for 6 over six months?</p> <p>7 A. I -- what I did is if they had a 8 meta-analysis, or whatever, I let the people that 9 were doing those studies track that, but pain was 10 listed as complications.</p> <p>11 Q. Okay. And how long did they track pain in 12 all of those studies?</p> <p>13 A. Some of the studies -- I'm going to have to 14 look so I don't misquote here.</p> <p>15 So I'm going to go to the Ward/Hilton, on 16 behalf of the UK and the Ireland QBT group, published 17 in 2007.</p> <p>18 I'm now going to go to Table 3, and this 19 was a response -- before and after five years of 20 surgery. Results are given in percentage reporting 21 system.</p> <p>22 On sexual questions, before surgery with 23 TTVT, they had 31 percent that complained of pain due 24 to dry vagina. Afterwards, that was 19 percent. 25 With colposuspension, it was 32 percent, and five</p>	<p>1 misstates.</p> <p>2 THE WITNESS: I did not do a systemic 3 review of the literature because it had already been 4 performed.</p> <p>5 BY MR. KUNTZ:</p> <p>6 Q. Do you know how many of these studies you 7 cite in your report you brought here today include 8 long-term pain as a data point?</p> <p>9 A. I think that it -- I can't say an actual 10 number, but when I look at the reports, if that was 11 included in their analysis and in their follow-up, 12 then, yes, I did.</p> <p>13 Q. Can you point me to a long-term randomized 14 controlled trial designed to look at the rate of 15 chronic pain following implantation of the TTVT 16 Retropubic device?</p> <p>17 A. There is no such study designed for that.</p> <p>18 Q. Can you point me to a long-term RCT 19 designed to look at the rate of chronic dyspareunia 20 following implantation of the TTVT Retropubic?</p> <p>21 A. I believe that you have numerous studies 22 that follow that. As in that being the absolute 23 endpoint of the study, no.</p> <p>24 Q. Can you hand to me or show me one long-term 25 RCT for TTVT that has safety as a primary endpoint?</p>
<p>Page 163</p>	<p>Page 165</p>

Michael P. Woods, M.D.

Page 166	Page 168
<p>1 BY MR. KUNTZ:</p> <p>2 Q. Would you agree that the pores in the</p> <p>3 Prolene TVT mesh can collapse increasing the risk for</p> <p>4 erosion and bridging fibrosis?</p> <p>5 MR. SNELL: Form.</p> <p>6 THE WITNESS: No.</p> <p>7 BY MR. KUNTZ:</p> <p>8 Q. Okay. You disagree with that?</p> <p>9 A. Yes.</p> <p>10 Q. Do you disagree with that same statement</p> <p>11 for Prolene mesh in general?</p> <p>12 A. I wasn't asked to evaluate Prolene mesh in</p> <p>13 general. I was asked to evaluate Retropubic TVT</p> <p>14 mechanically cut.</p> <p>15 Q. Okay. Have you ever read anything anywhere</p> <p>16 that the Prolene mesh -- used in any capacity the</p> <p>17 mesh can collapse and increase the risk for erosion</p> <p>18 and bridging fibrosis?</p> <p>19 A. I have read this; however, if it's an</p> <p>20 abdominal mesh, it wasn't what I was asked to review.</p> <p>21 TVT is a narrow strip, not a broad piece of material,</p> <p>22 and so that's almost like me telling I'm looking at</p> <p>23 my Model T and driving a Lamborghini. They're --</p> <p>24 they are two different things.</p> <p>25 Q. Okay. So you think mesh for the hernia is</p>	<p>1 polypropylene, Amid classification Type I,</p> <p>2 macroporous mesh. This is supported by SUFU, AUA,</p> <p>3 AUGS.</p> <p>4 BY MR. KUNTZ:</p> <p>5 Q. Do you agree that many physicians describe</p> <p>6 removing a sling as very difficult due to the amount</p> <p>7 of fibrosis?</p> <p>8 MR. SNELL: Form, objection.</p> <p>9 THE WITNESS: I have removed slings</p> <p>10 and I have found it to actually be much easier than</p> <p>11 such as an autologous swing because I cannot</p> <p>12 necessarily see the mesh, because it's completely</p> <p>13 incorporated, which is actually what I want, but what</p> <p>14 I do is I infiltrate with local anesthetic to develop</p> <p>15 tissue planes, and then I can take a nerve hook to</p> <p>16 catch the edge of the sling material, and then I can</p> <p>17 separate that off into -- and divide it. But when I</p> <p>18 pull that out, the tissue is completely incorporated</p> <p>19 into the material.</p> <p>20 BY MR. KUNTZ:</p> <p>21 Q. Have you ever talked to other physicians</p> <p>22 who have described removing the sling as difficult?</p> <p>23 MR. SNELL: Form.</p> <p>24 THE WITNESS: I have, and I've</p> <p>25 recommended some of the techniques that I have work</p>
Page 167	Page 169
<p>1 different than mesh for SUI?</p> <p>2 A. I believe that the design of the mesh and</p> <p>3 the cut is different, yes.</p> <p>4 Q. Do you know if the pores can collapse in</p> <p>5 the Prolene mesh when it's used for hernia</p> <p>6 application?</p> <p>7 A. I have seen Klinge -- one second here,</p> <p>8 where he talked about hernia mesh, but also in his</p> <p>9 2012 -- and I believe that is the right author. I --</p> <p>10 let me look here a minute because one of the things</p> <p>11 when I reviewed it, it was on abdominal mesh, but in</p> <p>12 his 2012 he stated that TVT was a macroporous</p> <p>13 monofilament mesh and that was a gold standard for</p> <p>14 stress incontinence. I'm just trying to remember who</p> <p>15 the author was. It was a German author. I may have</p> <p>16 to -- I may spend quite a bit of time looking for</p> <p>17 this. I may have to --</p> <p>18 Q. That's -- okay.</p> <p>19 Do you agree, in general, if pores are not</p> <p>20 large enough, it increases the risk of erosion?</p> <p>21 MR. SNELL: Form.</p> <p>22 THE WITNESS: I believe that the Amid</p> <p>23 classification Type I states that the macroporous</p> <p>24 mesh is -- has less erosion and is better suited with</p> <p>25 biocompatibility, that as long as it's a Prolene</p>	<p>1 for me.</p> <p>2 BY MR. KUNTZ:</p> <p>3 Q. Have you seen any internal Ethicon</p> <p>4 documents discussing the difficulty of removing</p> <p>5 slings?</p> <p>6 A. I -- I believe that there are internal</p> <p>7 documents that discuss the difficulty, but the idea</p> <p>8 is --</p> <p>9 Q. Sir, there's doctors that have difficulty</p> <p>10 removing slings. We can agree on that?</p> <p>11 MR. SNELL: Form, foundation.</p> <p>12 BY MR. KUNTZ:</p> <p>13 Q. Well, you tell them -- you tell them to use</p> <p>14 your technique and it's easy, right? So --</p> <p>15 A. If I --</p> <p>16 MR. SNELL: Same objection.</p> <p>17 Go ahead.</p> <p>18 THE WITNESS: I feel that physicians</p> <p>19 can have difficulty because it is fully incorporated.</p> <p>20 However, this is the design of it; this is actually</p> <p>21 what we wanted the tissues to do.</p> <p>22 BY MR. KUNTZ:</p> <p>23 Q. Do you believe that the mesh -- the Prolene</p> <p>24 mesh and the TVT can degrade?</p> <p>25 A. I'm not aware of -- when I'm looking at my</p>

## Michael P. Woods, M.D.

Page 170	Page 172
<p>1 high-level data that we are looking over time, that 2 we're not seeing any clinical implication of it. 3 Q. That wasn't my question. 4 I can't tell from your report. You say 5 everything degrades, Prolene mesh may degrade but no 6 clinical complications. I just want to know: As you 7 sit here today, do you believe that the Prolene mesh 8 in the TVT degrades or not? 9 A. I think that anything you implant in the 10 body can degrade over time. 11 Q. Okay. So the answer to my question is 12 "Yes"? 13 MR. SNELL: Form. 14 THE WITNESS: I believe that we have 15 50 years of data -- 16 BY MR. KUNTZ: 17 Q. That's not my question, Doctor, and you can 18 tell Mr. Snell all you want when he asks you 19 questions. My question simply is -- this is a yes or 20 no question. Does the Prolene mesh in the TVT 21 degrade? 22 A. From some of the internal documents, it 23 showed that there may have been some cracking noted, 24 but when they did other studies, it showed that -- 25 depends how you -- how you describe degrading, but --</p>	<p>1 people see any of the clinical evidence that there's 2 a problem with it, the answer is no. And that is 3 supported by the studies. 4 Q. You never reviewed or seen any studies 5 discussing clinical implications or problems with 6 degradation of mesh? 7 A. I have not. 8 Q. Were you supplied -- 9 A. I have seen from Taiwan where they removed 10 a suburethral sling that they had done surgery on and 11 they thought that there was some degradation there; 12 however, that is a very small case study. It doesn't 13 get into the level that I was asked to look at. 14 Q. Okay. So do you disagree with that paper? 15 A. I'm -- I am saying I was asked to review 16 the best evidence available, and that is on the 17 lowest tier. 18 Q. Okay. But did you -- did you -- did you 19 review -- so are you saying you didn't review any 20 articles that discussed degradation or degradation 21 causing clinical impact or you just haven't seen any? 22 A. When I saw the study from Taiwan where they 23 talked about it, but that is a small case series. 24 That is not the level -- when you have level of 25 evidence that's Level 1, that's a case series and a</p>
<p style="text-align: center;">Page 171</p> <p>1 and the chemical analysis showed that there was -- it 2 was not changed. So I am a little bit -- I feel that 3 personally anything you put in the body can age, just 4 as we do, but I have to look at it, is it clinically 5 significant. 6 Q. And we'll get to that. My question simply 7 is: Do you believe, yes or no, that the Prolene mesh 8 in the TVT degrades? 9 MR. SNELL: Objection, form. 10 THE WITNESS: I believe that over time 11 anything you can implant into the body can degrade. 12 BY MR. KUNTZ: 13 Q. So the answer to my question is "Yes"? 14 MR. SNELL: Form, objection. 15 THE WITNESS: I -- I would believe -- 16 I do not know the rate, but the potential would be 17 there, yes. 18 BY MR. KUNTZ: 19 Q. You state in your report that you're not 20 aware of any professional colleagues who have 21 expressed concerns about degradation; is that true? 22 A. That is correct. 23 Q. Did you do literature -- complete 24 literature search on degradation? 25 A. I -- when I go to the national meetings, do</p>	<p style="text-align: center;">Page 173</p> <p>1 very small case series. 2 Q. And your best evidence is a long-term, post 3 three years, randomized controlled trial, correct? 4 That's the best evidence? 5 A. And the SGS systemic reviews and 6 meta-analysis. 7 Q. As you sit here today, you've never been 8 provided or you've never reviewed any articles 9 suggesting degradation had any clinical 10 complications? 11 MR. SNELL: Form. 12 Go ahead. 13 THE WITNESS: I am unaware in the 14 high-level data that there's anything that suggests 15 that. 16 BY MR. KUNTZ: 17 Q. Okay. What about any data? Besides the 18 Taiwan study, the Wine (ph) study? 19 A. I have to look -- what I was charged with 20 was using the best medical evidence on the safety and 21 efficacy of the device, and that is randomized 22 controlled studies, systemic reviews, meta-analysis, 23 and I also look at data from national registries that 24 have -- or something like the Kaiser system, to pull 25 that data.</p>

Michael P. Woods, M.D.

Page 174	Page 176
<p>1 Q. What other registries? You mentioned a 2 couple in your report, right? 3 A. Yes. 4 Q. Okay. Like the Finnish registry? 5 A. The Austrian. 6 Q. Okay. How long did the Finnish registry 7 track complications? 8 A. I would have to pull that data. This may 9 take me a moment here. 10 MR. KUNTZ: Let's take a quick break. 11 (2:20 p.m. to 2:33 p.m. - Recess 12 taken.) 13 THE WITNESS: I viewed over at least 14 the one from Finland and that was a mediate 15 postoperative complication of two months. 16 BY MR. KUNTZ: 17 Q. And that is the Kuuva study? 18 A. Correct. 19 Q. So it tracked pain for -- postoperative 20 pain for two months -- 21 A. Correct. 22 Q. -- at a maximum? Okay. 23 Did you review the Tamussino Austrian 24 registry? 25 A. I will have to pull that up.</p>	<p>1 Q. You say on Page 8 of your report that the 2 mesh has antioxidants. 3 A. It is -- let me turn to Page 8, please. 4 And where -- oh, that's Page 9. Sorry. 5 It -- it's -- contains an antioxidant 6 package. 7 Q. Okay. Why do you want to prevent 8 oxidation? 9 A. There was -- when it comes to light, and 10 everything, that you want to make sure that it does 11 not become brittle. It is what I would kind of say. 12 Q. Would you believe that brittle mesh is 13 degraded mesh? 14 A. I haven't seen brittle mesh, so -- in a 15 patient and so I can't conjecture that. If I had a 16 piece of plastic that was sitting in the sun and I 17 folded it and it broke, I would say that was brittle. 18 Q. Would you say that's degraded? 19 A. I really don't know how I would call -- how 20 it's degraded, I mean. 21 Q. Is it -- is it possible to do a randomized 22 controlled trial to determine whether degradation 23 occurs? 24 A. I think that that would be very difficult 25 to do ethically, especially if you had patients that</p>
<p style="text-align: center;">Page 175</p> <p>1 Q. Okay. And we'll review that on the break. 2 Do you believe that you can see degradation 3 of the mesh clinically? 4 A. No. 5 Q. Okay. How do you define degradation? 6 A. I really don't define degradation of the 7 mesh. I -- when I look at it, if I am explanting it, 8 that would be something that I would send to the 9 pathologist so they'd be in formalin. 10 When they -- I cannot define when I'm 11 looking at it if it's degraded. 12 Q. Okay. Have you ever read any articles that 13 define degradation clinically -- 14 A. No. 15 Q. -- being able to see it with your own eyes? 16 A. No, I am not aware of a high-quality 17 article that shows that. 18 Q. Have you ever seen mesh that -- TV- -- 19 strike that. 20 Have you ever seen mesh in general that 21 you've pulled out that's brittle? 22 A. It's encapsulated in the tissue. 23 Q. Have you ever seen it when it's broken? 24 A. I have -- if it was broken, it's because I 25 cut the mesh to remove it.</p>	<p style="text-align: center;">Page 177</p> <p>1 were completely asymptomatic. 2 Q. Would you agree there's authors out there 3 or papers out there that have correlated pain to 4 degradation? 5 MR. SNELL: Form, objection. 6 THE WITNESS: They -- there are 7 authors that have suggested that. Again, what I need 8 is the level of evidence to show that that has 9 clinical implication and I have not found that. 10 BY MR. KUNTZ: 11 Q. Okay. So you disagree with those 12 suggestions or those papers? 13 A. I do not see any clinical evidence. 14 Q. So you disagree with those authors that 15 have suggested that? 16 A. I -- what I am saying is that I need a 17 level of study that would convince me otherwise. 18 Q. And I understand that and I understand that 19 you've never seen it in your practice of putting in 20 2,000 slings, correct? 21 A. Correct. 22 Q. But there are people who have written that 23 they've seen it and that they've correlated pain with 24 it; you understand that, right? 25 MR. SNELL: Objection, form.</p>

Michael P. Woods, M.D.

<p style="text-align: right;">Page 178</p> <p>1 BY MR. KUNTZ:</p> <p>2 Q. Have you seen --</p> <p>3 A. Again --</p> <p>4 Q. -- have you seen those papers?</p> <p>5 A. -- their eyes must be very different than 6 mine.</p> <p>7 Q. You've seen the papers and authors that 8 have suggested that, correct?</p> <p>9 MR. SNELL: Objection, form.</p> <p>10 THE WITNESS: It has been suggested by 11 the authors, so that would be expert opinion which 12 would be low-level data.</p> <p>13 BY MR. KUNTZ:</p> <p>14 Q. Okay. And you disagree with their 15 opinions?</p> <p>16 A. I do not have a quality of study that would 17 indicate that I would agree with that.</p> <p>18 Q. Okay. So you disagree with their opinions?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. How late do you believe that 21 erosions can occur in a patient with a TVT Retropubic 22 sling?</p> <p>23 A. Most of the studies show that they can 24 occur up to about two years. There are occasional 25 reports beyond that.</p>	<p style="text-align: right;">Page 180</p> <p>1 about TOPA. Do you recall that?</p> <p>2 A. Yes.</p> <p>3 Q. What is TOPA?</p> <p>4 A. TOPA was a compound mesh -- let me see. Do 5 you have the page that that's referred to?</p> <p>6 Q. Well, I can find it for you. I have it.</p> <p>7 A. This is on Page 21. I'm going to read 8 here. It says:</p> <p>9 Randomized clinical trials evaluating 10 meshes for the treatment of SUI do not support the 11 theory that a change in the design of TVT would 12 reduce or eliminate complications related to SUI. 13 I'm aware that Ethicon evaluated a lighter weight, 14 partially absorbable mesh called TOPA, but the 15 project was unsuccessful because the mesh was too 16 stretchy.</p> <p>17 Q. Why was Ethicon developing TOPA?</p> <p>18 A. They had lots of things in development, so 19 I -- I wasn't involved with this at all, but I know 20 at any one time they had multiple projects going on.</p> <p>21 Q. Okay. That wasn't my question. My 22 question was: Why was Ethicon developing TOPA?</p> <p>23 A. I do not have a valid --</p> <p>24 Q. Okay.</p> <p>25 A. -- answer.</p>
<p style="text-align: right;">Page 179</p> <p>1 Q. How far out do some of the occasional 2 reports go that show it longer than two years?</p> <p>3 A. I'm going -- I do not have an article 4 specifically in mind that looks at that.</p> <p>5 This may take me a little while here.</p> <p>6 Q. Let me ask you this, Doctor. Do you agree 7 that erosion can be a lifelong risk of a TVT 8 Retropubic device?</p> <p>9 A. I believe that if it has not happened by 10 about three years, the risk would be incredibly 11 small.</p> <p>12 Q. So you think most erosions, when they 13 occur, would occur within the three-year time period?</p> <p>14 A. Usually within the first six months, yes.</p> <p>15 Q. But up to three years?</p> <p>16 A. I believe there was one reference to that 17 as one report.</p> <p>18 Q. So three years is that the most time you've 19 ever seen for an erosion in the literature?</p> <p>20 A. That is my recollection.</p> <p>21 Q. And you're saying it can happen longer than 22 three years, but it's a very, very low percentage 23 possibility?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. You talked about, in your report,</p>	<p style="text-align: right;">Page 181</p> <p>1 Q. Did you review -- well, you didn't review 2 any test- -- deposition testimony from any employees 3 who worked on the TOPA project, correct?</p> <p>4 MR. SNELL: Objection: Form, asked 5 and answered.</p> <p>6 THE WITNESS: I did not review 7 depositions on those employees.</p> <p>8 BY MR. KUNTZ:</p> <p>9 Q. How many documents did you review related 10 to TOPA?</p> <p>11 A. I just reviewed over that they felt it was 12 too stretchy, and so --</p> <p>13 Q. That's what you remember reviewing?</p> <p>14 A. That...</p> <p>15 Q. What is Project Scion?</p> <p>16 A. That I am --</p> <p>17 Q. Have you ever heard of Project Scion?</p> <p>18 A. I don't know.</p> <p>19 Q. So that's a "No"?</p> <p>20 A. I am trying to -- I do not recall a Project 21 Scion.</p> <p>22 Q. Okay. What is Project Matrix? Have you 23 ever heard of Project Matrix?</p> <p>24 A. I do not recall a Project Matrix.</p> <p>25 Q. Did Ethicon ever -- do you know what a</p>

## Michael P. Woods, M.D.

Page 182	Page 184
<p>1 510(k) application is?</p> <p>2 A. Yes.</p> <p>3 Q. Did Ethicon ever submit a 510 application</p> <p>4 for the TOPA project?</p> <p>5 A. That I am not aware.</p> <p>6 Q. Okay. Did they ever submit one for the</p> <p>7 Matrix?</p> <p>8 A. I -- I was asked -- I was not asked to</p> <p>9 review their submissions. I was asked to review the</p> <p>10 medical literature.</p> <p>11 Q. Okay. Well, you have some other internal</p> <p>12 documents on your reliance list related to TOPA,</p> <p>13 right? And you talked about your understanding of</p> <p>14 what happened with TOPA and why it was canceled in</p> <p>15 your report, right?</p> <p>16 A. I said that it was too stretchy.</p> <p>17 Q. Okay. Did you review the 510(k) submission</p> <p>18 for project TOPA?</p> <p>19 A. No, I did not.</p> <p>20 Q. Did you review the 510(k) submission for --</p> <p>21 strike that.</p> <p>22 Do you know whether they submitted one for</p> <p>23 the Matrix project?</p> <p>24 A. I do not recall.</p> <p>25 Q. Do you know why the TOPA project was</p>	<p>1 total reviewing all of the internal documents?</p> <p>2 A. I would say that's correct, yes.</p> <p>3 Q. Okay. Did any of your ten-plus trips to</p> <p>4 the Ethicon headquarters or trips around the world</p> <p>5 for Ethicon, did you ever talk to any of the</p> <p>6 engineers or doctors who worked on the TOPA project?</p> <p>7 A. I -- I don't know who worked on the TOPA</p> <p>8 project in-depth, but I may have.</p> <p>9 Q. Okay. Do you know the size of the mesh</p> <p>10 that they used in the TOPA project?</p> <p>11 A. No, I do not.</p> <p>12 Q. Okay. Do you know the pore size?</p> <p>13 A. No, I do not.</p> <p>14 Q. Do you know the pore size of any other mesh</p> <p>15 besides the TVT Retropubic Prolene mesh?</p> <p>16 A. What I look for is an Amid classification</p> <p>17 Type I macroporous mesh.</p> <p>18 Q. Do you know the weight of the mesh used in</p> <p>19 TOPA?</p> <p>20 A. I -- my -- I -- when talk about weight or</p> <p>21 these things, my concern is that AUGS, SUFU,</p> <p>22 everybody has agreed that using the Amid</p> <p>23 classification Type I macroporous polypropylene mesh</p> <p>24 has the best safety profile and best integration.</p> <p>25 Q. Do you know the pore size of the mesh used</p>
Page 183	Page 185
<p>1 canceled?</p> <p>2 A. I -- I do not recall.</p> <p>3 Q. Do you know why the Matrix project was</p> <p>4 canceled?</p> <p>5 A. I do not recall.</p> <p>6 Q. Did you review any of the cadaver lab</p> <p>7 results for the TOPA project?</p> <p>8 A. I -- I do not recall. I reviewed a large</p> <p>9 amount --</p> <p>10 Q. If it's not on your -- if it's on your --</p> <p>11 if it's not on your reliance list, you didn't review</p> <p>12 it, correct?</p> <p>13 MR. SNELL: Objection, form.</p> <p>14 THE WITNESS: I reviewed a large</p> <p>15 number of things. I just don't recall them all.</p> <p>16 BY MR. KUNTZ:</p> <p>17 Q. You just remember the document that says it</p> <p>18 was too stretchy? You remember that one, right?</p> <p>19 A. I remember putting that into the...</p> <p>20 Q. But you don't remember any of the other</p> <p>21 documents you reviewed?</p> <p>22 A. I -- there was a large -- initially when I</p> <p>23 was doing this, I was reviewing internal documents</p> <p>24 and --</p> <p>25 Q. And I think you said you spent ten hours</p>	<p>1 in the Scion project?</p> <p>2 A. I do not recall it.</p> <p>3 Q. Do you know the weight of the mesh?</p> <p>4 A. I do not recall.</p> <p>5 Q. Do you know the material that was used?</p> <p>6 A. I do not recall.</p> <p>7 Q. Okay. You reference a Cammu (ph) study in</p> <p>8 your report?</p> <p>9 A. Cammu study? Yes.</p> <p>10 Q. What was that study?</p> <p>11 A. Let me -- I'm going to need to pull that</p> <p>12 study, please. Could we pull the Cammu study on the</p> <p>13 flash drive, please.</p> <p>14 Q. I wasn't even going to ask you about the</p> <p>15 study.</p> <p>16 MR. SNELL: He's not asking --</p> <p>17 BY MR. KUNTZ:</p> <p>18 Q. Yeah, maybe I'll clear up. Aside -- that's</p> <p>19 the only study, I believe, that you cite regarding</p> <p>20 the use of absorbable or lightweight meshes for SUI?</p> <p>21 A. Yes.</p> <p>22 MR. SNELL: Form, objection.</p> <p>23 Go ahead.</p> <p>24 BY MR. KUNTZ:</p> <p>25 Q. Have you reviewed any articles besides</p>

## Michael P. Woods, M.D.

<p style="text-align: right;">Page 186</p> <p>1 Cammu that discuss the use of absorbable mesh for the 2 treatment of SUI, in a sling?</p> <p>3 A. Actually, I can't cite a specific study, 4 but the Vicryl meshes that were used did not hold up 5 well.</p> <p>6 Q. Okay. When you do a native tissue repair, 7 do you use permanent or absorbable sutures?</p> <p>8 MR. SNELL: Form.</p> <p>9 THE WITNESS: I use permanent -- I use 10 permanent sutures if I attach the rectus and then 11 absorbable to attach the sling underneath the urethra 12 so it does not move the fascia.</p> <p>13 BY MR. KUNTZ:</p> <p>14 Q. Do you know who Brigitte Hellhammer is?</p> <p>15 A. I'm terrible with names.</p> <p>16 Q. Do you know who Boris Batke is?</p> <p>17 A. Again, I'm very terrible with names.</p> <p>18 Q. You testified earlier, I think, that you 19 have assumed some new positions recently?</p> <p>20 A. Yes.</p> <p>21 Q. What are those? Hold on. Are those on 22 your CV?</p> <p>23 A. No, they are not on my CV, so these are 24 new. These are within the last two weeks.</p> <p>25 I am medical director for the clinics at</p>	<p style="text-align: right;">Page 188</p> <p>1 BY MR. SNELL: 2 Q. So did you find dog studies, hernia 3 literature, hernia documents relevant to your 4 assessment of whether TTVT, when used in women for 5 treating incontinence, is reasonably safe?</p> <p>6 A. It wasn't relevant to what I was asked by 7 the judge to do.</p> <p>8 MR. KUNTZ: I'm just going to strike 9 that last comment. "Asked by the judge"?</p> <p>10 BY MR. SNELL: 11 Q. Did you get a copy of the judge's order 12 with regard what the parties -- 13 A. Yes. 14 Q. -- were supposed to focus on in this 15 particular case? 16 A. Yes. 17 Q. And I'm going to read it to you. This 18 question: Does the design of TTVT make the product 19 not reasonably safe for its intended use; is that 20 something you investigated? 21 A. Yes. 22 Q. All right. And what is TTVT's intended use? 23 A. It is strictly for the treatment of mixed 24 and stress urinary incontinence in women with 25 Retropubic approach.</p>
<p style="text-align: right;">Page 187</p> <p>1 Shenandoah Medical Center. I am now on the board for 2 an accountable care organization out of Des Moines.</p> <p>3 MR. KUNTZ: I think I'm done for right 4 now. You go ahead, Burt.</p> <p>5 MR. SNELL: All right.</p> <p>6 CROSS-EXAMINATION</p> <p>7 BY MR. SNELL:</p> <p>8 Q. Doctor, I have a few follow-up questions, 9 and then I'm going to go see if I can cover things by 10 topics.</p> <p>11 You were asked questions about whether you 12 reviewed certain hernia papers and documents or 13 animal studies, and I believe you testified that you 14 didn't find those relevant. Is that correct or not?</p> <p>15 MR. KUNTZ: Objection, leading.</p> <p>16 THE WITNESS: What I was tasked to do 17 was to review the relevant medical data for efficacy 18 and safety for Retropubic mechanically cut TTVT. And 19 when I looked at relevant data, I'm not operating on 20 dollars. I am not doing abdominal hernia repairs. 21 I'm having to look at the specific design of 22 Retropubic TTVT. So in looking at that data, that 23 doesn't impact the scientific and medical literature 24 for Retropubic TTVT.</p>	<p style="text-align: right;">Page 189</p> <p>1 Q. And you told Mr. Kuntz that you've used TTVT 2 Retropubic, correct? 3 A. Yes. 4 Q. For what was the intended use that you used 5 the TTVT Retropubic device? 6 A. Stress urinary incontinence and mixed 7 urinary incontinence. 8 Q. The judge's order at Page 5 says the 9 parties' primary focus should be the scientific and 10 medical literature suggesting or contesting that the 11 TTVT is defectively designed and that it is not 12 reasonably safe and can cause harm in women, 13 et cetera. Is that something you investigated? 14 MR. KUNTZ: Objection: Form and 15 leading. 16 THE WITNESS: Yes. And in doing so, 17 what I wanted to do is to look at the highest-level 18 evidence, which would be the randomized controlled 19 studies, the systemic reviews, the meta-analysis, and 20 cohort studies would be down that list, but anything 21 below that I felt was lower-level evidence that did 22 not pertain to this. 23 BY MR. SNELL: 24 Q. You mentioned a Dr. Klinge and I believe 25 you testified you saw where the plaintiffs' experts</p>

## Michael P. Woods, M.D.

Page 190	Page 192
<p>1 had looked at some of the literature or writings he 2 had done on hernias?</p> <p>3 A. Yes.</p> <p>4 Q. But you also testified that when it came to 5 the intended use of TTV and the application of TTV 6 for stress urinary incontinence, you had seen 7 something different by Dr. Klinge?</p> <p>8 A. Yes.</p> <p>9 Q. I'm going to hand you a -- one of the 10 Dr. Klinge's writings and we'll mark it for the 11 record.</p> <p>12 A. Okay. This is Page 440, Chapter 56, and it 13 says Alloplastic Implants for the Treatment of Stress 14 Urinary Incontinence and Pelvic Organ Prolapse.</p> <p>15 Q. What, if anything, did Dr. Klinge discuss 16 with regard to the use of TTV to treat stress urinary 17 incontinence?</p> <p>18 MR. KUNTZ: Objection.</p> <p>19 THE WITNESS: States that the -- at 20 the present, the gold standard for SUI surgery in 21 suburethral sling, using either tension-free tape or 22 transobturator tape. The initial concern is that the 23 mesh used might lead to high rates of erosion did not 24 hold true when macroporous polypropylene was used. 25 In two long-term trials, erosion rate was 1.7 and 3.1</p>	<p>1 A. Yes.</p> <p>2 Q. By Ford and some other authors?</p> <p>3 A. Yes.</p> <p>4 Q. We have it here tabbed. I can take it out 5 and mark it if counsel wants. Why don't we just do 6 that.</p> <p>7 (Exhibit No. 11 marked for 8 identification.)</p> <p>9 BY MR. SNELL:</p> <p>10 Q. So I'm handing you the -- is that the most 11 recent 2015 Cochrane review?</p> <p>12 A. Yes, this is.</p> <p>13 Q. What is a Cochrane review?</p> <p>14 A. Cochrane review is a government-sponsored 15 review to look at studies to develop recommendations 16 and to look at the quality of the studies.</p> <p>17 Q. You mentioned levels of evidence. Are 18 levels of evidence important in assessing whether the 19 TTV has utility and whether it's reasonably safe in 20 the intended use of treating stress urinary 21 incontinence?</p> <p>22 A. Absolutely. That's --</p> <p>23 Q. Why is that?</p> <p>24 A. That is the highest-level medical evidence 25 that is available and that's how I have to counsel my</p>
<p style="text-align: center;">Page 191</p> <p>1 percentage, respectively.</p> <p>2 BY MR. SNELL:</p> <p>3 Q. Does Dr. Klinge identify what type of mesh 4 the TTV mesh is for the intended use of treating 5 stress incontinence in women?</p> <p>6 A. It says the classical TTV Type I, 7 macroporous, monofilament, polypropylene mesh in the 8 same trial.</p> <p>9 Q. And what type of mesh is the TTV mesh used 10 to treat stress urinary incontinence in women?</p> <p>11 A. It is common Type I, macroporous, 12 monofilament, Prolene polypropylene mesh.</p> <p>13 Q. Is the Amid classification the current 14 standard for identifying the type of mesh for the 15 intended use of treating stress urinary incontinence?</p> <p>16 MR. KUNTZ: Objection.</p> <p>17 THE WITNESS: The national 18 organizations, including American Urology 19 Association, SUFU, AUGS, and also the NICE, all state 20 it is Amid classification Type I.</p> <p>21 (Exhibit No. 10 marked for 22 identification.)</p> <p>23 BY MR. SNELL:</p> <p>24 Q. Is one of the things that you reviewed the 25 most recent Cochrane review?</p>	<p style="text-align: center;">Page 193</p> <p>1 patients. This is how, when I am lecturing, I can 2 present the best data available, and the Cochrane 3 reviews and RCTs allow me to do that.</p> <p>4 Q. Are the Cochrane reviews, the RCT, the 5 systematic reviews you've mentioned by the AUA and 6 SGS reliable, in your opinion, in determining the 7 efficacy and the reasonableness of the safety of TTV 8 to treat stress urinary incontinence?</p> <p>9 A. Yes.</p> <p>10 MR. KUNTZ: Objection.</p> <p>11 THE WITNESS: The highest -- they are 12 the highest level of evidence.</p> <p>13 BY MR. SNELL:</p> <p>14 Q. And this new Cochrane review, if we turn to 15 Page No. 10, does the newest Cochrane review discuss 16 what is the standard for mesh classification to treat 17 stress urinary incontinence, mesh in women as of 18 2015?</p> <p>19 A. What they did is they broke down into 20 macroporous, microporous, macroporous multifilament, 21 and submicronic.</p> <p>22 (Reading:) And Type I mesh has the highest 23 biocompatibility for least propensity for infections. 24 Differences in their efficacy and complications are 25 likely due to several different factors including the</p>

## Michael P. Woods, M.D.

Page 194	Page 196
<p>1 different knits and weaves of the various tape  2 materials, their biomechanical properties and their  3 histologic biocompatibility. Pore size affects the  4 inflammatory response and resultant connective tissue  5 formation within and into the mesh, and the  6 rearrangement of the materials such as collagen  7 within the mesh structure. Macroporous meshes, pore  8 size in excess of 75 microns, easily allows  9 macrophages, leukocytes, fibroblasts, blood vessels  10 and collagen to transverse the pores, thus  11 macroporous meshes promote tissue host ingrowth with  12 resultant biocompatibility and low risk of infection.  13 Monofilament tapes are widely available and -- and  14 are now predominate in current clinical practice.</p> <p>15 Q. Did you assess the biocompatibility of the  16 TVT mesh utilized in the TVT device to treat stress  17 urinary incontinence?</p> <p>18 MR. KUNTZ: Objection.</p> <p>19 THE WITNESS: I assess it every day in  20 my patients and postoperatively.</p> <p>21 BY MR. SNELL:</p> <p>22 Q. And did you assess the medical literature  23 and the scientific literature with regard to the use  24 of the TVT and its biocompatibility in treating  25 stress urinary incontinence?</p>	<p>1 longer term on the follow-ups. These patients are  2 followed serially, and when we look at clinical  3 complications or clinical utility, is what is this  4 instance, is it acceptable as a surgeon, because  5 everything we do as a surgeon has potential risks and  6 complications.</p> <p>7 (Exhibit No. 12 marked for  8 identification.)</p> <p>9 BY MR. SNELL:</p> <p>10 Q. So you were discussing biocompatibility.  11 Are you a biomaterials expert with regard to  12 materials utilized in women to treat stress urinary  13 incontinence?</p> <p>14 MR. KUNTZ: Objection.</p> <p>15 THE WITNESS: Yes. I use it every  16 day. I am the end user, the implanter. And more  17 importantly for me is the implantee, and so when I  18 implant this in any woman, I have to use the best  19 available data to counsel that patient. And so in  20 being an end user, yes, I am.</p> <p>21 BY MR. SNELL:</p> <p>22 Q. Do you assess the biocompatibility of a TVT  23 device to treat stress incontinence in your patients  24 for whom you implant that device after implantation?</p> <p>25 MR. KUNTZ: Objection.</p>
Page 195	Page 197
<p>1 A. Yes, I did.</p> <p>2 Q. And what did you find?</p> <p>3 A. I found that the highest-level evidence  4 available in the medical literature, most of the  5 studies involve TVT Retropubic, the classical  6 mechanical cut.</p> <p>7 Q. And did the Cochrane reviews, the  8 systematic reviews, the incontinence guidelines show  9 whether or not TVT mesh to treat stress incontinence  10 in the TVT device is biocompatible?</p> <p>11 A. Yes.</p> <p>12 Q. And what did those Level 1 evidence show  13 overall in general with regard to the usefulness or  14 utility of the TVT?</p> <p>15 A. The randomized controlled studies, these  16 large studies, showed that the Retropubic TVT is the  17 most studied -- high-quality study of literally on a  18 urological gynecological procedure.</p> <p>19 Q. Did those studies demonstrate whether or  20 not the TVT is useful and that it is efficacious in  21 treating stress urinary incontinence?</p> <p>22 A. Yes.</p> <p>23 Q. Did those studies assess the safety of TVT  24 for the treatment of stress urinary incontinence?</p> <p>25 A. Yes, both in the short term and in the</p>	<p>1 THE WITNESS: Not only postoperatively  2 but at any follow-up visits; I always assess exit  3 wounds, the suburethral incision, and also the  4 trajectory along the urethra.</p> <p>5 BY MR. SNELL:</p> <p>6 Q. Do you assess the patient's reaction to the  7 mesh?</p> <p>8 A. I ask: "Is it working? Are you having  9 problems?" I ask specifically about voiding  10 dysfunction, pain, dyspareunia. That is my standard  11 questionnaires I have even if it's ten years ago and  12 I see them.</p> <p>13 Q. Do you do vaginal examinations on women for  14 whom you have implanted the TVT device to assess how  15 compatible that device is working in the woman's  16 body?</p> <p>17 A. I do because if there's an erosion or any  18 complication or even tenderness over the area.</p> <p>19 Q. I think you mentioned earlier the SGS, the  20 systematic review. I just want to mark that as  21 Exhibit 12. Is that the systematic review you were  22 earlier referencing?</p> <p>23 A. Yes.</p> <p>24 Q. And Table 3 has rates of complications for  25 various stress urinary incontinence procedures?</p>

Michael P. Woods, M.D.

Page 198		Page 200	
1 A. Yes.	1 Q. Does this report on the rates of pain in	2	2 sexual dysfunction with autologous slings, the
2 Q. And does that report on the Retropubic	3 Burches and the midurethral slings?	4	3 A. Yes.
3 TVT --	4 Q. And how does the midurethral sling,	5	5 particularly like the TVT Retropubic device to treat
4 A. Yes, it does.	6 stress urinary incontinence, compare to autologous	7	7 slings and the Burch for pain in sexual dysfunction
5 Q. -- applies to treat stress urinary	8 in women?	9	9
6 incontinence?	10 A. I will first go with Burch colposuspension,	11	10 percent, sexual dysfunction 3 percent. For
7 A. Yes.	12 autologous fascia without bone anchors, pain	13	13 10 percent, sexual dysfunction 8 percent. And for
8 Q. Is that something you relied upon in	14 mid- -- synthetic at midurethra, for pain 1 percent,	15	15 sexual dysfunction 0 percent.
9 formulating your opinions?	16 Q. So are the rates with TVT, the midurethral	17	17 sling, lower than the Burch and autologous --
10 A. In formulating -- yes.	18 A. Yes.	19	19 Q. -- for pain and sexual dysfunction?
11 Q. What level of evidence is the systematic	20 A. Yes.	21	21 Q. And is that consistent or inconsistent with
12 review?	22 your overall evaluation of the safety of midur- -- of	23	23 the TVT Retropubic sling to treat stress
13 A. This would be the highest level.	24 incontinence?	25	25 A. It is consistent with my literature review
14 Q. And what, if anything, does that systematic			
15 review show with regard to the risk of dyspareunia			
16 exposure and wound, you know, infection complications			
17 with TVT Retropubic compared to other procedures --			
18 MR. KUNTZ: Objection.			
19 BY MR. SNELL:			
20 Q. -- if anything?			
21 MR. KUNTZ: Objection.			
22 THE WITNESS: In the Retropubic			
23 approach, the incidence of dyspareunia of 0 percent.			
24 For return to operating room for erosion for			
25 pubovaginal -- excuse me, Retropubic sling would be			
Page 199		Page 201	
1 1.9 percent, pubovaginal 1.6. For incidence of	1 and also my personal experience.	2	2 (Exhibit No. 14 marked for
2 exposure, Retropubic was 1.4 percent and pubovaginal	3 identification.)	4	3
3 of 5.4 percent.	4 BY MR. SNELL:	5	4
4 BY MR. SNELL:	5 Q. I believe you earlier mentioned there were	6	5 some longer-term studies with the TVT Retropubic
5 Q. How is it that pubovaginal slings -- those	7	6	7 device?
6 are the autologous ones you mentioned earlier?	8 A. Yes.	8	8 Q. I want to show you a paper by the author
7 A. Yes.	9 Serati, S-E-R-A-T-I, et al.	9	9 It's been marked as Exhibit No. 14. Just I
8 Q. Can they erode into the body -- into a	10	10 first ask you: Is that a paper you've reviewed --	10
9 woman's body when used to treat stress incontinence,	11 A. Yes.	11	11 A. Yes.
10 as well?	12 Q. -- in your assessment of the TVT as a	12	12 device to treat stress urinary incontinence for
11 A. Yes.	13	13 women?	13
12 Q. What about wound infections or wound	14 A. Yes.	14	14 Q. And what, if anything, did that study show
13 complications?	15	15	15 with regard to the utility of TVT at ten years'
14 A. The wound infection rate for pubovaginal	16	16	16 duration?
15 sling, that would be Table 3--I just changed from	17 A. The ten-year subjective, objective, and	17	17 urodynamic cure rates were 89.7 percent,
16 Table 2--12 percent incidence for pubovaginal for	18	18	18 93.1 percent, and 91.4 percent.
17 wound infection.	19 Q. And how does -- strike that.	19	19 For a ten-year incontinence rate,
18 Q. Okay.	20	20	20
19 (Exhibit No. 13 marked for			
20 identification.)			
21 BY MR. SNELL:			
22 Q. I'm handing you Exhibit 13, which is			
23 Appendix A16 from the AUA guidelines, Complication			
24 Rates, No Prolapse. Do you see that?			
25 A. Yes.			

## Michael P. Woods, M.D.

<p style="text-align: right;">Page 202</p> <p>1 urodynamic, subjective cure rates around -- all 2 around 90 percent, what, if anything, does that tell 3 you about the long-term biocompatibility 4 intolerance of the TVT to treat stress 5 incontinence in women, if anything?</p> <p>6 MR. KUNTZ: Objection.</p> <p>7 THE WITNESS: That at ten years it is 8 still working as intended.</p> <p>9 BY MR. SNELL:</p> <p>10 Q. Is that data consistent or inconsistent 11 with the theory of degradation of the mesh?</p> <p>12 MR. KUNTZ: Objection.</p> <p>13 THE WITNESS: I do not -- this 14 reinforces the idea that clinically we do not see 15 degradation affecting outcomes.</p> <p>16 BY MR. SNELL:</p> <p>17 Q. I know you probably already testified. I 18 think you said that there is always a possibility 19 that something may happen considering our bodies as 20 they age. Do you recall giving testimony along those 21 lines?</p> <p>22 A. Yes.</p> <p>23 Q. Have you seen any reliable scientific 24 studies and evidence assessing TVT for the treatment 25 of stress urinary incontinence that show that that</p>	<p style="text-align: right;">Page 204</p> <p>1 In the past, before Retropubic TVT, when I 2 counseled my patients, I told them that over time 3 that there will be more failures. And this is one of 4 the reasons, when this came out, that I was really 5 looking at it. I wanted to make sure that we were 6 looking at long-term success rates. And the data 7 here, whether it's Nilsson's at 17 years, even though 8 that's not an RCT, this is long-term data, but when 9 you talk 17 years, 13 years, 10-plus years, the 10 success rates are in the 80s to 90s in these 11 patients. There are some that are a little bit lower 12 in the 70s but significantly better than anything I 13 could offer in the past.</p> <p>14 Q. And what is the patient satisfaction like 15 for the women who undergo implantation of TVT 16 Retropubic to treat their stress urinary 17 incontinence?</p> <p>18 MR. KUNTZ: Objection.</p> <p>19 THE WITNESS: I ask my patients when 20 they come in: "How are you doing?" And, "Would you 21 recommend this to your friend, your sister, an 22 acquaintance?" And almost always it is, yes, that 23 the impact in their life was immediate. That's one 24 of the reasons the impact on these women's lives from 25 the surgical procedure is so profound that it's one</p>
<p style="text-align: right;">Page 203</p> <p>1 product degrades?</p> <p>2 MR. KUNTZ: Objection.</p> <p>3 THE WITNESS: No. No, I am not aware 4 of any.</p> <p>5 BY MR. SNELL:</p> <p>6 Q. And do the long-term studies that you have 7 reviewed on TVT support the contention that the mesh 8 degrades?</p> <p>9 A. No, it does not. It does not impact the 10 clinical utility.</p> <p>11 Q. Turn, if you would, at Page 39 of your 12 expert report. Just so I have a copy, let me --</p> <p>13 At Page 39 of your report, did you assess 14 the long-term literature with regard to TVT and its 15 intended use to treat stress urinary incontinence?</p> <p>16 A. For Retropubic TVT, yes, I did.</p> <p>17 Q. And on Page 39 at the top, do you discuss 18 multiple different studies that assess the TVT 19 Retropubic device in the treatment of stress 20 incontinence in women?</p> <p>21 A. Yes.</p> <p>22 Q. What do those studies show, if anything, in 23 your mind?</p> <p>24 A. What this shows in the long term that the 25 continence rates still maintain over time.</p>	<p style="text-align: right;">Page 205</p> <p>1 of the most rewarding things I've done.</p> <p>2 BY MR. SNELL:</p> <p>3 Q. On Page 39 of your report, do you assess 4 the randomized control trials and clinical studies 5 that assess TVT in the treatment of stress urinary 6 incontinence in women?</p> <p>7 A. Yes.</p> <p>8 Q. And in particular, did you assess what the 9 patient satisfaction rates were with TVT?</p> <p>10 A. Yes.</p> <p>11 Q. And can you just in general summarize your 12 overall impression about, you know, what rate of 13 patient satisfaction was there in the literature that 14 you have accumulated on Page 39 of your report?</p> <p>15 A. From the low 80s all of the way up to the 16 upper 90s satisfaction rates.</p> <p>17 Q. Is that consistent or inconsistent with 18 your clinical experience?</p> <p>19 A. That is --</p> <p>20 MR. KUNTZ: Objection.</p> <p>21 THE WITNESS: That is very consistent 22 with my clinical.</p> <p>23 BY MR. SNELL:</p> <p>24 Q. What, if anything, does the 80 to 25 90 percent patient satisfaction rate, even in</p>

## Michael P. Woods, M.D.

Page 206	Page 208
<p>1 long-term follow-up, say with regard to the  2 biocompatibility of the TVT device in women when used  3 to treat stress incontinence?</p> <p>4 MR. KUNTZ: Objection.</p> <p>5 THE WITNESS: That it is still  6 continuing to work and that they are not having  7 complications that are affecting their lives.</p> <p>8 BY MR. SNELL:</p> <p>9 Q. I think you told Mr. Kuntz, earlier you had  10 used different types of meshes in the application,  11 the intended use to treat stress urinary  12 incontinence?</p> <p>13 A. Yes.</p> <p>14 Q. And can you just tell us, again: What's  15 your -- what different types of meshes have you  16 utilized to treat stress incontinence over your  17 career?</p> <p>18 A. Mersilene, Gore-Tex. I did use a couple  19 hand-knitted Vicryl meshes. And each of those just  20 did not seem to work.</p> <p>21 Q. In your assessment of the literature, did  22 you examine whether there was any mesh that had been  23 demonstrated to be more biocompatible than the TVT  24 Retropubic mesh in the treatment of stress urinary  25 incontinence?</p>	<p>1 please.</p> <p>2 MR. SNELL: Yeah, that's a bad  3 question.</p> <p>4 BY MR. SNELL:</p> <p>5 Q. Have you seen in the medical literature  6 whether non-Type I macroporous meshes, such as  7 multifilament meshes, have lower efficacy than TVT?</p> <p>8 A. Yes.</p> <p>9 Q. Have you evaluated the literature to assess  10 whether the multifilament meshes and the non-Type I  11 meshes have higher complication rates than the Type I  12 TVT mesh you've been talking about today?</p> <p>13 A. Yes, not only in literature but personal  14 experience.</p> <p>15 Q. Okay. And what does that literature show  16 with regard to the meshes other than TVT that are  17 non-Type I?</p> <p>18 A. Much high erosion rates is one of the big  19 things, along with pain and infections.</p> <p>20 Q. And does the literature describe why those  21 higher complications are seen with the design of  22 those meshes as compared to the design of the TVT  23 Retropubic mesh?</p> <p>24 A. I have to go back to the Amid  25 classification where you have macroporous mesh size</p>
<p style="text-align: center;">Page 207</p> <p>1 MR. KUNTZ: Objection.</p> <p>2 THE WITNESS: I did not find anything  3 that was more biocompatible. Also, you have  4 something that has been utilized in humans for over  5 50 years, along with FDA changing from a Class 3 to a  6 Class 2 for Prolene. I have also assessed as I used  7 to do a significant number of tubal reversals, and  8 I've seen those patients laparoscopically, and  9 looking at where the sutures are located laparo--  10 these are small sutures, but the body of the  11 literature shows tremendous biocompatibility.</p> <p>12 BY MR. SNELL:</p> <p>13 Q. Has any mesh been demonstrated in reliable  14 scientific evidence to have either higher success  15 than the TVT Retropubic device to treat stress  16 urinary incontinence -- go with that one, first.</p> <p>17 A. I am unaware of any device or any mesh that  18 has a better subjective and objective cure rate or  19 improvement rate in the literature.</p> <p>20 Q. Have you seen, in Cochrane reviews and  21 other meta-analyses, where mesh has -- or devices  22 other than the bottom-up TVT actually have lower  23 efficacy than TVT?</p> <p>24 MR. KUNTZ: Objection.</p> <p>25 THE WITNESS: Could you rephrase that,</p>	<p style="text-align: center;">Page 209</p> <p>1 of at least 75 microns so the body can integrate in  2 and around and through the mesh.</p> <p>3 Q. Are you an expert in the design of TVT  4 Retropubic and, in particular, for assessing the  5 utility and safety of it for its intended use to  6 treat stress incontinence?</p> <p>7 MR. KUNTZ: Objection.</p> <p>8 THE WITNESS: Yes. I have taught  9 numerous surgeons the procedure, so on that aspect, I  10 may not be a chemical engineer but, on that,  11 absolutely. Also, in the development of these  12 products, I worked with the engineers as an end user  13 for my input.</p> <p>14 BY MR. SNELL:</p> <p>15 Q. Did you read the medical literature with  16 regard to the design and development of TVT by  17 Drs. Ulmsten and Petros and determine whether or not  18 in the design of TVT to treat incontinence those  19 surgeons tried other materials besides the Prolene  20 polypropylene?</p> <p>21 A. Yes, they --</p> <p>22 MR. KUNTZ: Objection.</p> <p>23 BY MR. SNELL:</p> <p>24 Q. And what, if anything, did that data show  25 with regard to the other materials that they tried to</p>

Michael P. Woods, M.D.

Page 210	Page 212
<p>1 use in the TVT device to treat stress incontinence?</p> <p>2 A. With the Type -- Type III meshes, that they</p> <p>3 found significantly higher erosion rate, and that</p> <p>4 very much correlates to my own personal experience</p> <p>5 with this.</p> <p>6 Q. Do you know whether they had tried meshes,</p> <p>7 such as Gore-Tex, before the Prolene?</p> <p>8 A. Gore-Tex and Marlex mesh were two of the</p> <p>9 ones that they did utilize. And then they also then</p> <p>10 looked at the polypropylene meshes at that point, and</p> <p>11 they did a study where they had in the arms of Marlex</p> <p>12 and polypropylene macroporous.</p> <p>13 Q. Do you know if those doctors in the design</p> <p>14 of TVT Retropubic device to treat stress incontinence</p> <p>15 also assessed a mesh called Mersilene?</p> <p>16 A. Yes.</p> <p>17 Q. And what was found with Mersilene in the</p> <p>18 design of TVT?</p> <p>19 A. A significant erosion rate.</p> <p>20 Q. You were asked some questions about</p> <p>21 mechanical cut and laser cut mesh. Have you used</p> <p>22 both of those different types of cutting of the TVT</p> <p>23 mesh?</p> <p>24 A. Yes.</p> <p>25 Q. In your opinion, does -- and just so that</p>	<p>1 Mr. Kuntz that you had seen company documents and</p> <p>2 testing where they had mesh and was stretching it on</p> <p>3 clamps?</p> <p>4 A. Yes.</p> <p>5 Q. Is that the use of TVT to treat stress</p> <p>6 incontinence, that testing?</p> <p>7 A. No, that's benchtop testing. That has</p> <p>8 really nothing to do when I'm implanting the mesh.</p> <p>9 That's an actual deliberate deformation. I don't</p> <p>10 understand all of the properties there, but it does</p> <p>11 not impact when I place it in a patient.</p> <p>12 Q. When you place a TVT Retropubic device and</p> <p>13 that mesh in a patient, is there a sheath on the</p> <p>14 mesh?</p> <p>15 A. Yes.</p> <p>16 Q. Is the pathway by which the mesh and the</p> <p>17 sheath travel, do they follow a trocar?</p> <p>18 A. Yes.</p> <p>19 Q. Do you believe that benchtop testing of a</p> <p>20 mesh -- and when you saw the benchtop testing, let me</p> <p>21 ask you this, was the sheath on the mesh?</p> <p>22 A. No.</p> <p>23 Q. Was the trocar on the mesh?</p> <p>24 A. No.</p> <p>25 Q. Do you believe that that benchtop testing</p>
<p style="text-align: center;">Page 211</p> <p>1 everyone is clear, when a mesh is mechanic -- let's</p> <p>2 focus on the TVT mesh and not the other meshes you</p> <p>3 say are not relevant.</p> <p>4 When you cut the TVT mesh, where are you</p> <p>5 cutting it when you're mechanically or laserly</p> <p>6 cutting it?</p> <p>7 MR. KUNTZ: Objection.</p> <p>8 THE WITNESS: On the edges.</p> <p>9 BY MR. SNELL:</p> <p>10 Q. The very edge?</p> <p>11 A. Yes.</p> <p>12 Q. Is the mesh still about 1 centimeter wide?</p> <p>13 A. Yes.</p> <p>14 Q. Does the cutting of the mesh, either</p> <p>15 mechanically or with a laser, change the way the mesh</p> <p>16 handles and operates in the body when used to treat</p> <p>17 stress incontinence?</p> <p>18 A. I do not feel that either way impacts how I</p> <p>19 implant or how I treat my patients afterwards. The</p> <p>20 longest-term data I have is mechanical cut.</p> <p>21 Q. And what does that long-term data show with</p> <p>22 regard to the mechanical cut TVT mesh?</p> <p>23 A. The complication rates are very low and</p> <p>24 that the long-term success rates are very robust.</p> <p>25 Q. Now, I think you mentioned to Mr. -- or</p>	<p style="text-align: center;">Page 213</p> <p>1 in stretching the mesh without the sheath is</p> <p>2 consistent with the intended use of the TVT device to</p> <p>3 treat stress incontinence?</p> <p>4 MR. KUNTZ: Objection.</p> <p>5 THE WITNESS: The sheath is on the</p> <p>6 mesh and that because it is on the mesh that is its</p> <p>7 intended use, and so the sheath needs to be present</p> <p>8 from a clinical standpoint and an implantation</p> <p>9 standpoint for Retropubic TVT.</p> <p>10 BY MR. SNELL:</p> <p>11 Q. And whether it's a mechanical cut mesh or a</p> <p>12 laser cut mesh, is the mesh, when it's put into the</p> <p>13 body of a woman in the intended use of stress</p> <p>14 incontinence, encased in a sheath?</p> <p>15 A. Yes.</p> <p>16 Q. Do any of the stress urinary incontinence</p> <p>17 guidelines or the analyses and position statements by</p> <p>18 the professional societies state that there is any</p> <p>19 clinically significant difference between mechanical</p> <p>20 and laser cut TVT mesh?</p> <p>21 MR. KUNTZ: Objection.</p> <p>22 THE WITNESS: No. No, they do not.</p> <p>23 BY MR. SNELL:</p> <p>24 Q. Have you assessed the literature before</p> <p>25 2007?</p>

Michael P. Woods, M.D.

<p style="text-align: center;">Page 214</p> <p>1 A. Yes.</p> <p>2 Q. Have you been assessing the literature</p> <p>3 since 2007 with regard to TTV?</p> <p>4 A. Yes.</p> <p>5 Q. Is there any clinically significant</p> <p>6 difference that you have seen in the medical</p> <p>7 literature before and after laser cut was an option</p> <p>8 with regard to the utility or safety of TTV?</p> <p>9 MR. KUNTZ: Objection.</p> <p>10 THE WITNESS: I've seen no differences</p> <p>11 in the literature.</p> <p>12 BY MR. SNELL:</p> <p>13 Q. Is consistency in the literature something</p> <p>14 you look to as a scientist?</p> <p>15 A. As a scientist and as a clinician.</p> <p>16 Q. Why is that important, if at all?</p> <p>17 A. What you have to do is you have to have</p> <p>18 reproducibility. Just as you have -- in baseball you</p> <p>19 have people who are phenomenal pitchers. In medicine</p> <p>20 you also have phenomenal surgeons, but you have to</p> <p>21 have the randomized control reproducible studies in</p> <p>22 order to be able to draw a conclusion.</p> <p>23 Q. And do you believe -- and I think you</p> <p>24 discussed in many pages of your report the reliable</p> <p>25 scientific evidence you found. Did you believe was</p>	<p style="text-align: center;">Page 216</p> <p>1 perioperative and intraoperative complications.</p> <p>2 Q. Okay. So did you assess the safety of TTV,</p> <p>3 not just within the perioperative setting but also</p> <p>4 postoperatively, including years of follow-up?</p> <p>5 A. Yes, and then when we look at these RCTs</p> <p>6 and we look at the follow-up, that is part of what we</p> <p>7 are assessing, is are we having new onset of</p> <p>8 complications. You know, we like to look at the</p> <p>9 safety perioperatively, but we also want to make sure</p> <p>10 that in the long run it continues to work well.</p> <p>11 And the level of evidence -- one of the</p> <p>12 reasons I looked at suburethral slings was when I</p> <p>13 looked at my patients and I did a major procedure, I</p> <p>14 would have to look them in the eye and say, I'll</p> <p>15 probably see you back. And the redos of Burches</p> <p>16 are -- can be very, very difficult procedures. And I</p> <p>17 use slings as my backup for that, but I, again,</p> <p>18 harvesting autologous slings and complications that</p> <p>19 occur with that, also the bigger incisions, I was</p> <p>20 always looking for the better, and even today, I'm</p> <p>21 hoping that we can find a better TTV.</p> <p>22 Q. Is there -- you were -- I think you told</p> <p>23 plaintiffs' counsel you were doing the Burch and you</p> <p>24 had done autologous slings long before TTV to treat</p> <p>25 stress incontinence?</p>
<p style="text-align: center;">Page 215</p> <p>1 in -- was relevant and important in assessing the</p> <p>2 design of TTV?</p> <p>3 A. Absolutely.</p> <p>4 Q. Are the long-term ten-year -- strike that.</p> <p>5 Are the majority of the 5-, 7-, 10-, out to</p> <p>6 17-year, the longer-term studies with TTV, do those</p> <p>7 studies utilize mechanically cut mesh?</p> <p>8 A. The longer terms are all mechanically cut.</p> <p>9 Q. And what, if anything, do they show about</p> <p>10 the utility and safety of the mechanical cut TTV</p> <p>11 mesh?</p> <p>12 MR. KUNTZ: Objection.</p> <p>13 THE WITNESS: They state that the</p> <p>14 efficacy continues and that we do not see increasing</p> <p>15 erosions or anything along or other complications</p> <p>16 with that, so --</p> <p>17 BY MR. SNELL:</p> <p>18 Q. Go ahead. I didn't mean to cut you off.</p> <p>19 A. It implies very strongly that -- when I'm</p> <p>20 counseling my patients, that I can look at them in</p> <p>21 the eye and say, the 10-year data up to 17 years,</p> <p>22 variability and rate, that it looks like this is</p> <p>23 going to last you in the long term.</p> <p>24 And when I'm talking with my patient,</p> <p>25 that's what she needs to know, along with the</p>	<p style="text-align: center;">Page 217</p> <p>1 A. That is correct.</p> <p>2 Q. As we sit here today, is there even more</p> <p>3 data on the TTV Retropubic device to treat</p> <p>4 incontinence than there are for those older Burch and</p> <p>5 pubovaginal slings?</p> <p>6 A. Much better high-level quality evidence.</p> <p>7 Q. Going back to the Exhibit 14, the Serati</p> <p>8 10-year TTV paper, did those authors assess the</p> <p>9 safety of TTV even out at ten years?</p> <p>10 A. Yes.</p> <p>11 Q. And what did they find, if anything, that</p> <p>12 is significant to you?</p> <p>13 A. This is on Page 942, European Urology, and</p> <p>14 it would be 61 and 2012:</p> <p>15 No patient required tape release or section</p> <p>16 during the ten-year follow-up. No significant pelvic</p> <p>17 organ prolapse, vaginal, bladder, or urethral</p> <p>18 erosion, or de novo dyspareunia were noted in the</p> <p>19 remaining 58 patients.</p> <p>20 Q. What's the importance of that, if anything,</p> <p>21 to you in your overall assessment of the safety of</p> <p>22 the design of the TTV Retropubic device?</p> <p>23 A. That years down the road I've not seen</p> <p>24 complications and my patients are not experiencing</p> <p>25 that.</p>

## Michael P. Woods, M.D.

Page 218	Page 220
<p>1       Q. Plaintiffs' counsel asked you some  2       questions earlier about your usage of TTV and how  3       many TTVs you had done, correct?  4       A. Yes.  5       Q. And I believe you testified the number was  6       2,000, give or take 500?  7       A. Yes.  8       Q. Are you certain that's how many TTVs you've  9       placed over your career?  10      A. All TTVs?  11      Q. The TTV Retropubic device?  12      A. The TTV Retropubic device --  13            MR. KUNTZ: Objection.  14            THE WITNESS: -- I would say is about  15       in that range.  16       BY MR. SNELL:  17       Q. For example, did you undergo any training  18       or exposure to the TTV Retropubic before you began  19       utilizing it as an option --  20      A. Yes.  21      Q. -- for stress incon --  22      A. Yes.  23      Q. And did you keep track of how frequently  24       you did TTV Retropubic devices once you began doing  25       it on a monthly or yearly basis?</p>	<p>1       your patients in order to assess whether or not they  2       had complications after the TTV Retropubic device?  3       A. Yes.  4            MR. KUNTZ: Objection.  5       BY MR. SNELL:  6       Q. Is that actually something -- strike that.  7            Did you follow your patients who you put --  8       who you did a Burch procedure or an autologous sling  9       or some other type of non-Type I macroporous sling  10       and to treat incontinence?  11       A. Yes.  12       Q. Did you follow them to see if they had  13       complications?  14       A. Yes.  15       Q. Did you track those complications?  16       A. In my -- I did not put them necessarily on  17       paper, but in the patient record I would have that.  18       Q. This is your -- is this your general  19       medical recollection and knowledge of complications  20       that your patients have?  21       A. Yes. I would -- I would -- the only time I  22       would look at specific complications is if I was  23       doing a study.  24       Q. Okay. And did you assess the overall  25       medical literature and data that you found to be</p>
<p style="text-align: center;">Page 219</p> <p>1       MR. KUNTZ: Objection.  2       THE WITNESS: I kept a running mental  3       log.  4       BY MR. SNELL:  5       Q. Just like you would have kept a running  6       mental log of how many Burches or autologous slings  7       you did --  8       A. Yes.  9       Q. -- before that?  10      A. Yes.  11      Q. The fact that you didn't write down the  12       exact number you did in a certain month or year, does  13       that make your estimate unreliable with regard to the  14       number of TTV Retropubic devices that you have used  15       in your career?  16       MR. KUNTZ: Objection.  17       THE WITNESS: No. I think that it's a  18       ballpark figure that is probably fairly close.  19       BY MR. SNELL:  20       Q. Such that there is no doubt in your mind  21       whatsoever that you -- do you believe you have  22       extensively used the TTV Retropubic device to treat  23       stress incontinence in women?  24       A. Yes.  25       Q. For your complication rates, did you follow</p>	<p style="text-align: center;">Page 221</p> <p>1       scientifically reliable to ascertain the rates of  2       complications with TTV Retropubic device?  3       MR. KUNTZ: Objection, asked and  4       answered, at least eight times.  5       MR. SNELL: Well, I'll withdraw if  6       he's answered it.  7       MR. KUNTZ: I mean, it's in his report  8       and he's answered ten times.  9       THE WITNESS: Please repeat that, if  10       you would. I -- it was a little long, so please  11       restate it. It's getting towards the end of the day.  12       BY MR. SNELL:  13       Q. Okay. Did you assess the medical  14       literature that you found to be scientifically  15       reliable and valid with regard to what were the  16       complication rates following a TTV device --  17       Retropubic device placed to treat stress  18       incontinence?  19       A. Yes.  20       Q. Did you also look at the literature to  21       assess how those rates compared to rates with the  22       Burch colposuspension or the autologous sling?  23       A. Yes, and I wanted to expound a little bit  24       on that, is when we look at these complication rates,  25       this is over a 26-year history of treating women, and</p>

Michael P. Woods, M.D.

<p style="text-align: center;">Page 222</p> <p>1 so when I'm looking at older data comparing -- early 2 on in my career, I may have pulled up Burch's initial 3 paper on it, and I'm looking to see, am I hitting in 4 that area, or I would talk to Ray Lee and say, "I've 5 seen this. What should be the expected rates?"</p> <p>6 And so this is a 26-year evolution. When I 7 was in residency, randomized controlled studies 8 really were not the norm.</p> <p>9 Q. As we sit here today, there are, I think 10 you've testified, numerous randomized controlled 11 studies on the TVT Retropubic device?</p> <p>12 A. Yes.</p> <p>13 Q. Is there any other device or procedure to 14 treat stress urinary incontinence for which there is 15 more randomized control trial data than the TVT 16 Retropubic device?</p> <p>17 A. No.</p> <p>18 Q. You were asked questions about some of the 19 registries. At Pages 33 through 36 in your report, 20 do you cite to and discuss some of the registries, 21 like the Schraffordt registry that had three years 22 follow-up?</p> <p>23 A. Yes.</p> <p>24 Q. And did you look at another registry by 25 Nilsson that reported 12-month data from over 2,000</p>	<p style="text-align: center;">Page 224</p> <p>1 standard, is that what you were referring to earlier? 2 A. Yes.</p> <p>3 Q. And if you look at -- turn back to the back 4 to Table 4.</p> <p>5 A. Table 4, yes.</p> <p>6 Q. Do they report on long-term outcomes -- 7 complications such as mesh exposure, voiding 8 difficulties, things of that nature?</p> <p>9 A. It's ten years and then they look at 10 voiding residuals, they look at mesh exposure rate, 11 subjective voiding difficulties; and then they also 12 break it down -- the subjective voiding difficulties 13 into slow stream or intermittency, position-dependent 14 micturition, need to immediately re-void, incomplete 15 bladder emptying feeling, straining to void, 16 hesitancy.</p> <p>17 Q. It says asymptomatic vaginal mesh exposure, 18 there was one patient equaling 0.3 percent; do you 19 see that?</p> <p>20 A. That is, yes.</p> <p>21 Q. What, if anything, does that tell you about 22 the long-term safety of TVT Retropubic device in the 23 treatment of stress urinary incontinence?</p> <p>24 MR. KUNTZ: Objection.</p> <p>25 THE WITNESS: What that tells me is</p>
<p style="text-align: center;">Page 223</p> <p>1 TVT patients?</p> <p>2 A. Yes.</p> <p>3 Q. You also cite to Svenningsen, 4 S-V-E-N-N-I-N-G-S-E-N. What was the follow-up with 5 that TVT registry?</p> <p>6 A. That says ten-year results.</p> <p>7 Q. And what did that study show with regard to 8 the long-term ten-year biocompatibility of the TVT 9 Retropubic device?</p> <p>10 A. Objective cure rate was 89.9 percent, 11 excuse me, subjective cure rate of 76.1 percent, 12 82.6 percent of patients stated they were very 13 satisfied with their surgery. And also in 14 Svenningsen it said, "Midurethral slings are 15 currently considered the gold standard in the 16 surgical treatment of SUI."</p> <p>17 (Exhibit No. 15 marked for 18 identification.)</p> <p>19 BY MR. SNELL:</p> <p>20 Q. Okay. So you've been handed Exhibit 15. 21 Is this the ten-year TVT study that you referenced on 22 Page 35 of your expert report?</p> <p>23 A. Yes.</p> <p>24 Q. And on the first page, first paragraph, 25 where they talk about midurethral slings are the gold</p>	<p style="text-align: center;">Page 225</p> <p>1 we're not seeing exposure over the long run which we 2 saw with other meshes.</p> <p>3 BY MR. SNELL:</p> <p>4 Q. Other meshes such as what?</p> <p>5 A. Marlex mesh.</p> <p>6 THE WITNESS: Can I ask if I can have 7 a bathroom break?</p> <p>8 MR. SNELL: Yes, you may. Go ahead. 9 (3:39 p.m. to 3:44 p.m. - Recess 10 taken.)</p> <p>11 BY MR. SNELL:</p> <p>12 Q. You were shown Exhibit 9. It was a 13 contract dated November 23rd, 2010. You -- do you 14 recall that?</p> <p>15 A. Yes.</p> <p>16 Q. My question is simple. This contract says 17 that it shall continue to January 31st, 2012. Do 18 see that in Paragraph 1?</p> <p>19 A. Yes.</p> <p>20 Q. Is this a 2010 prof. ed. contract or a 2011 21 contract?</p> <p>22 A. It would be -- so that would be for the 23 year 2011.</p> <p>24 Q. Okay. You were asked questions about, you 25 know, moneys you were paid, you know, in your</p>

Michael P. Woods, M.D.

<p style="text-align: center;">Page 226</p> <p>1 consulting for Ethicon. Let me ask you. And I think 2 a question was asked were you paid during your 3 travel. My question to you is this. Were you paid 4 for your time for when you left your house or your 5 office until you returned?</p> <p>6 A. No.</p> <p>7 Q. How were you compensated or reimbursed as a 8 consultant?</p> <p>9 A. I am not sure of what year that they 10 started paying for travel time, but it was very late 11 in this whole cycle. But if I traveled two days but 12 only did a half day of lecture, I got paid a half 13 day, so I was two days out of the office in that 14 case. But when I drove to the airport, when I was on 15 the plane, checking in at a hotel, getting a cab, I 16 was not reimbursed for any of that time.</p> <p>17 Later on, they actually did a travel time, 18 but that -- I don't remember what year that kicked 19 in, but it wasn't for the vast majority of the time.</p> <p>20 Q. Can you give us your best estimate, would 21 that have been within the last five years or was 22 that --</p> <p>23 A. I would probably say --</p> <p>24 Q. Just let me get my question in. 25 -- was that when you began doing consulting</p>	<p style="text-align: center;">Page 228</p> <p>1 A. I'll go ahead and read this paragraph. 2 This is Page 772. This is a Journal of Minimally 3 Invasive Gynecology. 4 Q. Is this a study you've seen, first of all? 5 A. Yes. 6 Q. Okay. 7 A. And -- 8 Q. Go ahead. 9 A. -- Volume 18, No. 6. 10 It says: 11 Dyspareunia occurred only in patients who 12 underwent TTV Secur procedure. The pain was relieved 13 after surgical removal of the involved tape segment. 14 Dyspareunia associated with the TTV Secur procedure 15 might be explained in part by the rigidity and 16 reduced flexibility of the synthetic polypropylene 17 implant because it is laser cut, which tends to 18 result in a stiff edge -- tape edge. As a result, 19 the overlying vaginal mucosa is constantly 20 traumatized, much more than it would be with use of a 21 mechanically cut tape. 22 Q. So plaintiffs' counsel asked you if you had 23 seen any studies, and I want to focus now on: Have 24 you seen any scientifically reliable studies 25 assessing TTV in the treatment of stress urinary</p>
<p style="text-align: center;">Page 227</p> <p>1 on the TTV Retropubic device? 2 A. No. It would have been after that time. 3 Q. You, I believe, earlier stated it was 4 financially challenging for the consulting work at 5 times. Did I hear you correctly or did I not? 6 A. Yes. 7 Q. What did you mean by that? 8 A. I was in solo practice so my overhead 9 stayed the same whether I was there or not, and so I 10 had ongoing expenses, and if those weren't 11 reimbursed -- you know, if I was gone the two days, I 12 got reimbursed for half a day, and my ongoing 13 expenses were not covered. 14 (Exhibit No. 16 marked for 15 identification.)</p> <p>16 BY MR. SNELL: 17 Q. Take a look at this. I've handed you 18 Exhibit 16. It's a study by Neuman. Turn, if you 19 would, to the second-to-last page where it talks 20 about dyspareunia in the TTV Secur group. 21 A. Yes. 22 Q. Do you see where the authors say or they 23 paused that there may have been more dyspareunia in 24 the laser cut mesh which tends to result in a stiff 25 tape edge. Do you see that?</p>	<p style="text-align: center;">Page 229</p> <p>1 incontinence where any author in the world stated 2 there were higher complications with the mechanical 3 cut TTV mesh compared to some other form of cut mesh? 4 MR. KUNTZ: Objection. 5 THE WITNESS: I am not aware of any 6 studies. 7 BY MR. SNELL: 8 Q. And in your assessment of the overall 9 literature for devices to treat stress urinary 10 incontinence, particularly meshes, did you find any 11 other device that used an alternative to mechanical 12 cut mesh that had a better safety profile than the 13 TTV Retropubic mechanically cut mesh? 14 MR. KUNTZ: Objection. 15 THE WITNESS: No. 16 BY MR. SNELL: 17 Q. Did you provide professional education on 18 the TTV Retropubic device to treat stress 19 incontinence? 20 A. Yes. 21 Q. Did you provide that to other surgeons? 22 A. Yes. 23 Q. Did you talk to other surgeons about the 24 design of the TTV Retropubic device? 25 A. Yes.</p>

Michael P. Woods, M.D.

<p style="text-align: center;">Page 230</p> <p>1 Q. Did you talk to other surgeons about the 2 components of the TVT design? 3 A. Yes. 4 Q. Did you explain to other surgeons the 5 importance or lack thereof, if any, to the various 6 components of the TVT Retropubic device? 7 A. Yes. 8 Q. Did you discuss the importance, if any, 9 with the sheath utilized in the TVT device? 10 A. Yes. 11 Q. Was the sheath an important design element 12 of the TVT Retropubic device? 13 A. Yes, and I would like to expound a little 14 bit upon this. 15 Q. Go for it. 16 A. When I initially looked at TVT Retropubic, 17 I was very concerned about the possibility of 18 bacterial contamination. 19 Having the sheath there somewhat alleviated 20 that, but what -- when I was looking at this, I was 21 thinking, if we have bacterial contamination, we'll 22 be seeing infections very rapidly; and I didn't see 23 that. 24 I also had spoken with the surgeons when 25 they were using Gore-Tex patches for hernias, and</p>	<p style="text-align: center;">Page 232</p> <p>1 published two-year results concluding that 2 midurethral surgery for stress urinary incontinence 3 significantly improved sexual function, and neither 4 synthetic mesh sling route that was studied was 5 associated with increased dyspareunia. 6 Q. Does the reliable scientific evidence that 7 you have assessed on the TVT device in the intended 8 use of treating stress incontinence when it has with 9 the sheath and the trocars, the entire device, show 10 that there is a significant risk of the mesh roping? 11 A. No. 12 MR. KUNTZ: Objection. 13 BY MR. SNELL: 14 Q. Or the mesh curling? 15 A. No. 16 MR. KUNTZ: Objection. 17 BY MR. SNELL: 18 Q. Of fraying? 19 A. No. 20 MR. KUNTZ: Objection. 21 BY MR. SNELL: 22 Q. Of pore collapse? 23 A. No. 24 Q. Of degradation? 25 MR. KUNTZ: Objection.</p>
<p style="text-align: center;">Page 231</p> <p>1 they were finding an increased infection rate and 2 were they seeing that with the polypropylene mesh. 3 So in that evolution, I was looking at what 4 the Amid classification said, what my surgeons were 5 saying. Also having that plastic sheath did provide 6 a little bit more of what I would call comfort in 7 looking at it. At this point, I'm very comfortable 8 with the mesh, but I -- I had mesh complications of 9 other types that I was very concerned about. 10 Q. And were those all meshes that had -- 11 A. They were -- 12 Q. -- either a smaller pore than the TVT mesh 13 or they were non-Type I Amid, microporous, 14 monofilament meshes? 15 A. They were all non-Type I on the 16 classification. However, once burned, twice shy. 17 Q. At Page 80 of your expert report, do you 18 discuss the different literature and data you found 19 to be reliable with regard to TVT and its effects on 20 sexual function -- 21 A. Yes. 22 Q. -- in addition to the AUA and the SGS 23 guidelines? 24 A. Yes. (Reading) 25 Urinary Incontinence Treatment Network</p>	<p style="text-align: center;">Page 233</p> <p>1 THE WITNESS: No. 2 BY MR. SNELL: 3 Q. Of pore collapse? 4 A. No. 5 Q. Of a lack of biocompatibility? 6 A. No. 7 Q. And the paragraph on Page 80 of your expert 8 report, with regard to the alleged defects that the 9 plaintiffs' experts have raised -- you saw the 10 different claims that the plaintiffs' experts made in 11 their expert reports, and I'm focusing specifically 12 on Drs. Blaivas, Dr. Elliott, and Dr. Rosenzweig. 13 A. Okay. 14 Q. Did you -- you've read their reports? You 15 saw the claims they make? 16 A. Yes, yes. 17 Q. Do you believe that they assessed the 18 reliable scientific literature with regard to the 19 safety of TVT and its intended use to treat stress 20 incontinence in formulating those opinions? 21 A. The level of evidence was not Level 1. 22 Q. And their reliance on hernia literature or 23 non-TVT Retropubic studies, did you find those to not 24 be relevant? 25 A. Not relevant to what I was tasked with</p>

Michael P. Woods, M.D.

Page 234	Page 236
<p>1 Retropubic TTV. Retropubic TTV mesh was not used in  2 abdominal hernia. In an abdominal hernia large sheet  3 of mesh is not used in TTV.</p> <p>4 Q. You were asked about, would you disagree  5 with a surgeon who said that it was difficult to  6 tension the mesh or -- do you recall those questions  7 in general --</p> <p>8 A. Yes.</p> <p>9 Q. -- about would you disagree if a surgeon  10 said this?</p> <p>11 A. That's that surgeon's opinion. I may  12 disagree with it, but it's his opinion.</p> <p>13 Q. Right. My question to you, though, is:  14 Would that surgeon's statement or opinion, how would  15 that rank on the level of evidence, the evidence  16 pyramid, compared to the data upon which you  17 primarily relied?</p> <p>18 MR. KUNTZ: Objection.</p> <p>19 THE WITNESS: That would be an expert  20 opinion, so very low level.</p> <p>21 BY MR. SNELL:</p> <p>22 Q. And is that called anecdotal evidence?</p> <p>23 A. Yes.</p> <p>24 Q. And in order to assess the overall utility  25 and safety of the TTV device in the treatment of</p>	<p>1 BY MR. SNELL:  2 Q. And is the long-term data that you cited to  3 and you have reviewed relevant to your analysis in  4 that regard --</p> <p>5 A. Yes.</p> <p>6 Q. -- if at all?</p> <p>7 Why is that?</p> <p>8 A. When we are looking at long-term rates, do  9 we see an increase, do -- these are all things that  10 are we are assessing, safety, tissue compatibility,  11 in a very clinical aspect.</p> <p>12 Q. And when you talk about the long-term  13 studies, are you talking about TTV Retropubic device  14 studies, or are you talking about some other device  15 or application?</p> <p>16 A. No, Retropubic TTV mechanically cut.  17 (Exhibit No. 17 marked for  18 identification.)</p> <p>19 BY MR. SNELL:  20 Q. I've handed a five-year randomized control  21 trial by Laurikainen that looked at the TTV  22 Retropubic device. Are you familiar with that?</p> <p>23 A. Yes.</p> <p>24 Q. This is a study you've read and relied  25 upon?</p>
<p style="text-align: center;">Page 235</p> <p>1 stress incontinence, you need to look at the highest  2 level of evidence; is that what you've testified?</p> <p>3 A. Yes.</p> <p>4 Q. Because anecdotal evidence, case reports,  5 do they establish causation?</p> <p>6 A. Not at all.</p> <p>7 Q. Can you apply those to the population  8 abroad so that you can derive incidence?</p> <p>9 A. No.</p> <p>10 Q. And is it fair to say you -- I'll withdraw  11 that one.</p> <p>12 Are you aware of any reliable scientific  13 literature that shows that TTV, when treating  14 patients for stress urinary incontinence, actually  15 does degrade?</p> <p>16 MR. KUNTZ: Objection.</p> <p>17 THE WITNESS: I'm not aware of any  18 high-level evidence.</p> <p>19 BY MR. SNELL:</p> <p>20 Q. Or that even if one were to assume it  21 degraded there is any clinically significant effect?</p> <p>22 MR. KUNTZ: Objection.</p> <p>23 THE WITNESS: I would agree that we do  24 not see clinical effect even if it were to degrade.</p>	<p style="text-align: center;">Page 237</p> <p>1 A. Yes.</p> <p>2 Q. Is this a study that you considered in the  3 formulation of your opinions in this matter?</p> <p>4 A. Yes.</p> <p>5 Q. And is this the TTV Retropubic device that  6 you have been discussing that you assessed the  7 utility and safety of here?</p> <p>8 A. Yes.</p> <p>9 Q. If you'd turn to the Results section. I  10 just have a quick question. Let me ask you. Let's  11 back up, I'm sorry. Look to the first page.</p> <p>12 It says 95 percent of the included women  13 were assessed at five years.</p> <p>14 A. Yes.</p> <p>15 Q. How does that number -- what is the  16 significance, if anything, about 95 percent follow-up  17 in a five-year randomized trial?</p> <p>18 A. That -- this was phenomenal follow-up and,  19 also, that the surgeons were able to assess these  20 patients. There was only a 5 percent dropout rate.  21 That's -- that's very nice.</p> <p>22 Q. And in this study, how did the TTV perform  23 from a utility and a usefulness standpoint?</p> <p>24 A. I'll read the Results section. It says:  25 Results and limitations: A total of</p>

Michael P. Woods, M.D.

Page 238	Page 240
<p>1 95 percent of the included women could be assessed  2 according to the protocol five year after surgery.  3 The objective cure rate was 84.7 percent in the TVT  4 group and 86.2 percent in the TVT-O group, with no  5 statistical difference between the groups.  6 Subjective treatment satisfaction was 94.2 percent in  7 the TVT group and 91.7 in the TVT-O group, with no  8 differences between groups. Complication rates were  9 low, and no difference between groups.</p> <p>10 Q. So what does a subjective treatment  11 satisfaction rate of 94 percent, if anything, tell  12 you about the long-term biocompatibility of the TVT  13 device?</p> <p>14 A. At five years out, the patients are very  15 happy with the results.</p> <p>16 Q. Turn to the Results section right above  17 Discussion.</p> <p>18 A. Okay.</p> <p>19 Q. You mentioned that it says complication  20 rates were low. What's the significance of that, if  21 anything, with regard to the safety and  22 biocompatibility of the TVT Retropubic device?</p> <p>23 A. That if there were problems with  24 biocompatibility, we would start to see erosions and  25 we would start to see pain and these kind of things.</p>	<p>1 study in your opinion?</p> <p>2 A. Yes.</p> <p>3 Q. And this five-year, long-term randomized  4 control trial -- and, again, is that the highest  5 level of evidence?</p> <p>6 A. Yes, it is.</p> <p>7 Q. Were there any tape extrusions in the TVT  8 Retropubic group?</p> <p>9 A. No.</p> <p>10 Q. And what, if anything, does that inform you  11 of with regard to the safety and biocompatibility of  12 the TVT Retropubic design?</p> <p>13 MR. KUNTZ: Objection.</p> <p>14 THE WITNESS: That the design showed  15 that there was no evidence of mesh erosions in this  16 well-done study.</p> <p>17 BY MR. SNELL:</p> <p>18 Q. Does this study speak to the safety of the  19 TVT Retropubic device in its design?</p> <p>20 A. Absolutely, and this is actually one of the  21 studies I quote when I talk to my patients.</p> <p>22 Q. And is this study consistent or  23 inconsistent with your opinion that the TVT -- strike  24 that.</p> <p>25 Is this study consistent or inconsistent</p>
Page 239	Page 241
<p>1 Q. In the paragraph above Discussion, it  2 reports -- it says, "No women had any sign of tissue  3 reaction, erosion, or tape protrusion at their  4 five-year follow-up." Did I read that?</p> <p>5 A. That is correct.</p> <p>6 Q. What is the significance, if anything, of  7 that?</p> <p>8 A. That at five years out we're not seeing  9 problems with mesh erosion or signs of infection or  10 decreasing function.</p> <p>11 Q. And it said, During the course of the  12 study, two women experienced tape problems. Both  13 were in the TVT-O arm but not the TVT Retropubic arm,  14 correct?</p> <p>15 A. Let me read this one:</p> <p>16 During the course of the study, two women  17 experienced tape problems, both in the TVT-O arm.  18 One woman had a tape extrusion one year  19 postoperatively. The midline visible part of the  20 tape was excised, resulting in incontinence, and she  21 later had a TVT operation. One woman had retention  22 problems and the tape was cut in the midline twice,  23 which resolved the retention, but she experienced  24 urgency symptoms.</p> <p>25 Q. So in this five-year -- is this a long-term</p>	<p>1 with your opinion, as stated in your expert report,  2 that the design of the Retropubic TVT is safe for its  3 intended use to treat stress incontinence?</p> <p>4 A. Yes.</p> <p>5 Q. Is it consistent or inconsistent?</p> <p>6 A. It is very consistent with my --</p> <p>7 Q. Okay. I forgot my question. I apologize,  8 Doctor. Sometimes I forget myself.</p> <p>9 Plaintiffs' counsel, Mr. Kuntz, asked you  10 questions about your experience with different design  11 aspects of different devices, particularly, you know,  12 devices that you had consulted on or had some  13 involvement in the design, meeting with the  14 engineers, things like that.</p> <p>15 A. Yes.</p> <p>16 Q. Were there any other devices that you have  17 been involved in the design assessment or the safety  18 assessment that you did not mention to Mr. Kuntz?</p> <p>19 A. I honestly don't remember what I mentioned  20 to Mr. Kuntz --</p> <p>21 Q. Okay.</p> <p>22 A. -- but with Coloplast, I was consulted on  23 their single-incision sling with the anchoring  24 mechanism. With AMS, I also was consulted for their  25 anchoring mechanism on their single-incision sling.</p>

## Michael P. Woods, M.D.

<p style="text-align: right;">Page 242</p> <p>1 Dr. Stephen Singh of Australia consulted me on a 2 Colpotomizer that he was developing and subsequently 3 obtained FDA clearance. And then, also, with my work 4 with LigaSure, which I think we discussed.</p> <p>5 Q. Okay. When you provide professional 6 education on the TVT Retropubic device, would you 7 educate surgeons on the instructions for use?</p> <p>8 A. Yes.</p> <p>9 Q. Would you take surgeons step by step 10 through the instructions of use and how to adequately 11 and properly employ the design of the TVT Retropubic 12 device?</p> <p>13 MR. KUNTZ: Objection.</p> <p>14 THE WITNESS: Yes. Also, at the, 15 especially, cadaver labs, and things, is we actually 16 had copies of the IFU that we would hand them.</p> <p>17 BY MR. SNELL:</p> <p>18 Q. Okay. You were asked some questions by 19 Mr. Kuntz about, well, if a surgeon said that 20 removing a mesh was difficult, would you disagree 21 with him; do you recall a question along those lines?</p> <p>22 A. Yes.</p> <p>23 Q. Let me ask you this -- and I think you told 24 Mr. Kuntz. You have done excisions of mesh slings, 25 correct?</p>	<p style="text-align: right;">Page 244</p> <p>1 those patients were charged. 2 And if there was a 1 centimeter extrusion, 3 what I would do in those cases is I would infiltrate 4 local anesthetic to separate the vaginal epithelium 5 from the underlying tissues, go approximately 6 5 millimeters laterally and incise that tissue and 7 infiltrate the local anesthetic on each side and 8 remove the mesh.</p> <p>9 Q. And I think you said -- you've published on 10 treating tape exposures?</p> <p>11 A. I have presented. 12 Q. Presented. Fine. 13 A. Yes. 14 Q. Have you published or presented on the lack 15 of any biocompatibility in non-Type I -- Amid Type I 16 meshes?</p> <p>17 A. I -- the paper that I -- the case report 18 paper would be a publication.</p> <p>19 Q. And when you did professional education on 20 the TVT Retropubic device, did you also assess and 21 discuss with surgeons whether that mesh was an Amid 22 Type I mesh or not?</p> <p>23 A. Yes. 24 Q. And what, if anything, did you tell the 25 surgeons with regard to whether or not it was an Amid</p>
<p style="text-align: right;">Page 243</p> <p>1 A. Yes. 2 Q. Have you done an excision or release of the 3 TVT Retropubic device sling?</p> <p>4 A. Yes. 5 Q. Was that a difficult procedure in your 6 experience?</p> <p>7 A. No. 8 Q. Why do you say "No"?</p> <p>9 A. I could do it in the office under local 10 anesthetic.</p> <p>11 But in going back to that surgeon is if 12 they had a difficult time, I would try to offer, 13 "Here's what I've done; this may make it easier and 14 safer for you and your patient." And so if they 15 would sit back and say, "Hey, I'm having a problem 16 with this," I would say -- sit back and say, "Well, 17 here's what I've done that made it easier," and so 18 it's always an educational process on that.</p> <p>19 Q. How would treating a TVT Retropubic mesh 20 exposure compare in difficulty to having to go back 21 and treat a Burch voiding dysfunction problem?</p> <p>22 A. They're not -- they're not even in the same 23 league. You know, I would bring a patient in. I did 24 an abstract on just treating it with laser treatment 25 in the office under local anesthetic of which none of</p>	<p style="text-align: right;">Page 245</p> <p>1 Type I mesh? 2 A. Oftentimes, I go back to my Gore-Tex mesh, 3 it was just one of those big things in your life, but 4 what I would do is I would say that the Amid 5 classification Type I macroporous mesh allows the 6 body, macrophages, blood vessels, to incorporate into 7 that tissue and actually allow it to reinforce the 8 prior damaged tissues.</p> <p>9 Q. The macrophages, the blood vessels for 10 incorporation for tissue healing?</p> <p>11 A. And fibroblasts. Yes. 12 Q. Is that something you learned about during 13 your surgical training and residencies?</p> <p>14 A. I actually had a strong interest in 15 microsurgery early on in my career, so we did look at 16 healing defects and trying to figure out why some 17 women had more scarring than others. And then, 18 again, specifically with Retropubic TVT, with that 19 mesh, I had had very negative experiences with Marlex 20 mesh, Mersilene, and I was very hesitant.</p> <p>21 Q. How does the strength of the evidence and 22 the medical literature, assessing the safety and 23 utility of TVT, compare to the literature assessing 24 Burch and autologous?</p> <p>25 MR. KUNTZ: Objection.</p>

Michael P. Woods, M.D.

<p>1                   THE WITNESS: Most of the Burch and 2 autologous slings are case series expert opinion 3 which would be low-level evidence.</p> <p>4 BY MR. SNELL:</p> <p>5                   Q. Is the TTV evidence of a higher level 6 overall than the Burch or autologous pubovaginal 7 slings if one looks across --</p> <p>8                   A. If you look at --</p> <p>9                   Q. -- the reliable literature?</p> <p>10                  A. If you look at the total number of RCTs, 11 et cetera, overwhelmingly Retropubic TTV has the 12 highest-quality evidence.</p> <p>13                  MR. SNELL: Okay. Thank you.</p> <p>14                  REDIRECT EXAMINATION</p> <p>15 BY MR. KUNTZ:</p> <p>16                  Q. Doctor, just a couple of questions.</p> <p>17                  You went over, again, these mental lists 18 you keep of how many surgeries you've performed and 19 these mental logs of how many erosions you've had and 20 mental logs of reoperations, correct?</p> <p>21                  A. Yes.</p> <p>22                  Q. So you're good at keeping mental logs over 23 a ten-year period of time of your surgeries --</p> <p>24                  A. Yes.</p> <p>25                  Q. -- revisions, correct?</p>	<p>1                   engin- -- I don't recall the name of the engineers at 2 Coloplast or at AMS.</p> <p>3                   Q. Okay. How many meetings did you have with 4 Dan Smith about the TTV Retropubic device?</p> <p>5                   A. Formal meetings and when I was there to 6 talk with him?</p> <p>7                   Q. Let's start with formal.</p> <p>8                   A. I don't think on TTV Retropubic I had any 9 formal meetings with him.</p> <p>10                  Q. Okay. What about informal meetings?</p> <p>11                  A. I would sit down and talk with him, 12 especially I wanted to find out how they came up with 13 the design of the trocar, how they chose the angles; 14 I was just fascinated by those things and, you know, 15 the cadaveric studies and these things. I wanted to 16 know a little bit more about that.</p> <p>17                  Q. You had cited some RCTs and went over them 18 on Page 39 of your report.</p> <p>19                  A. Okay.</p> <p>20                  Q. Tell me which one of those RCTs is laser 21 cut mesh and which one is mechanical cut mesh.</p> <p>22                  A. We can -- the older ones would all be 23 mechanical cut.</p> <p>24                  Q. What do you mean by "older"?</p> <p>25                  A. So we would talk about Ward, Valpas, Lee.</p>
<p>Page 247</p> <p>1                  A. Yes.</p> <p>2                  Q. Okay. What's your mental log tell you of 3 how much you've been paid by Ethicon over the last 11 4 years as an consultant?</p> <p>5                  A. Because I did not see those checks, that 6 went to my office manager and accounts. I --</p> <p>7                  Q. Who was your office manager.</p> <p>8                  A. Arlone Farber.</p> <p>9                  Q. She's still your office manager?</p> <p>10                 A. No.</p> <p>11                 Q. So --</p> <p>12                 A. When I took my --</p> <p>13                 Q. So you don't have a mental log of how much 14 money you've made from Ethicon over the last 11 15 years?</p> <p>16                 A. No, I do not.</p> <p>17                 Q. That's just a mental log you don't keep 18 like you do everything else?</p> <p>19                 A. Correct.</p> <p>20                 Q. Okay. You had said you'd worked with some 21 engineers as an end user of the TTV Retropubic 22 device?</p> <p>23                 A. Yes.</p> <p>24                 Q. What engineers?</p> <p>25                 A. What's Dan -- Dan Smith would be one. The</p>	<p>Page 249</p> <p>1                  I would have to look at Rinne and Palva on whether 2 they -- their data was gathered pre-2007.</p> <p>3                  Q. So as we sit here today, you don't know 4 whether Rinne, Palva, Laurikainen, Wai, Khan, or Ross 5 involved laser cut or mechanical cut mesh, correct?</p> <p>6                  A. That is correct.</p> <p>7                  Q. And you've kept your documentation of the 8 money you've made from Ethicon for the last seven 9 years you told me, correct?</p> <p>10                 A. I think it would be available. I don't 11 personally have it.</p> <p>12                 Q. Okay. But you can get the last seven 13 years?</p> <p>14                 A. I believe I can.</p> <p>15                 Q. Okay. You had said that you consult --</p> <p>16                 or --</p> <p>17                 MR. SNELL: I'm going to object to 18 producing that, but that's just for my record.</p> <p>19                 THE WITNESS: Okay.</p> <p>20                 (Discussion off the record.)</p> <p>21                 MR. KUNTZ: I'm not talking about 22 1099s. We're talking about summations. And if you 23 want to do that, then we'll -- let's just -- let's go 24 gold, man, let's just go all of them. I'll do a 25 trade any day of the week you want to do it for our</p>

Michael P. Woods, M.D.

<p style="text-align: center;">Page 250</p> <p>1 guys for your people.</p> <p>2 MR. SNELL: That would get your boy</p> <p>3 Dan Elliott fired who claims he's supposed to be</p> <p>4 working as an expert.</p> <p>5 MR. KUNTZ: Do something about it.</p> <p>6 Talk is cheap.</p> <p>7 MR. SNELL: I'm not a dirty pool</p> <p>8 player.</p> <p>9 BY MR. KUNTZ:</p> <p>10 Q. Doctor, you told me that you consulted with</p> <p>11 your patients and you tell them about the 11- and</p> <p>12 17-year data.</p> <p>13 A. Yes, I did.</p> <p>14 Q. Do you tell your patients that?</p> <p>15 A. Yes, I do.</p> <p>16 Q. Okay.</p> <p>17 A. And when it was earlier data, I would sit</p> <p>18 back and say, "This is the longer follow-up on</p> <p>19 these."</p> <p>20 Q. Okay. Do you tell them that when you're</p> <p>21 advising them to have the TTV product implanted?</p> <p>22 A. I -- I inform them that there is studies up</p> <p>23 to 11 -- 17 years --</p> <p>24 Q. Okay.</p> <p>25 A. -- that have --</p>	<p style="text-align: center;">Page 252</p> <p>1 A. There's data up to 17 years.</p> <p>2 Q. Okay. Do you tell them that they might be</p> <p>3 getting a laser cut mesh that doesn't have 17-year</p> <p>4 data to support it?</p> <p>5 MR. SNELL: Objection, form.</p> <p>6 THE WITNESS: No, I just say the TTV</p> <p>7 products.</p> <p>8 BY MR. KUNTZ:</p> <p>9 Q. Okay. Do you tell them after that --</p> <p>10 A. No.</p> <p>11 Q. -- after you find out you give them the</p> <p>12 laser cut mesh?</p> <p>13 A. No.</p> <p>14 Q. Do you go back and tell them, "Hey, I was</p> <p>15 wrong. You got the laser cut mesh. There's not</p> <p>16 17-year data to support it"?</p> <p>17 MR. SNELL: Objection: Argumentative,</p> <p>18 misstates. He's already told you it's the same mesh,</p> <p>19 regardless in his opinion. So you're trying to make</p> <p>20 a mountain out of a molehill.</p> <p>21 BY MR. KUNTZ:</p> <p>22 Q. No. You know -- you said the 17-year data</p> <p>23 and 11-year data does not apply to the laser cut mesh</p> <p>24 earlier today in this deposition, did you not?</p> <p>25 MR. SNELL: I think that misstates his</p>
<p style="text-align: center;">Page 251</p> <p>1 Q. And do you tell them that in your office or</p> <p>2 the day of the surgery?</p> <p>3 A. In my office.</p> <p>4 Q. Okay. So you tell your patients that may</p> <p>5 end up getting the laser cut mesh that there's</p> <p>6 17-year data to support it?</p> <p>7 A. What I tell them is that with the TTV</p> <p>8 products --</p> <p>9 Q. Oh, okay.</p> <p>10 A. -- that there's up to 17-year data.</p> <p>11 Q. Okay. Do you tell them that the 17- and</p> <p>12 11-year data doesn't apply to laser cut that they</p> <p>13 might get but you won't know until the day of the</p> <p>14 surgery that they're getting laser cut?</p> <p>15 A. No, I just say the TTV products.</p> <p>16 Q. Okay. Do you think that's fair? Do you</p> <p>17 think it's fair to tell your patient that there's 17-</p> <p>18 and 11-year data when that data doesn't exist for</p> <p>19 laser cut mesh?</p> <p>20 MR. SNELL: Objection, misstates.</p> <p>21 BY MR. KUNTZ:</p> <p>22 Q. Well, let's walk through this, Doctor. You</p> <p>23 tell them in your office before they get to surgery</p> <p>24 that there -- for the TTV products there's 17- and</p> <p>25 11-year data?</p>	<p style="text-align: center;">Page 253</p> <p>1 testimony.</p> <p>2 BY MR. KUNTZ:</p> <p>3 Q. Did you not say that?</p> <p>4 A. I believe that it does not and --</p> <p>5 Q. Okay. Do you go back and tell your</p> <p>6 patients they got a laser cut mesh, that you don't</p> <p>7 know -- you said, under oath, that you don't know</p> <p>8 until the day of the surgery they're getting laser</p> <p>9 cut mesh. Do you go back and tell them that the 17-</p> <p>10 and 11-year data doesn't support the product that you</p> <p>11 implanted?</p> <p>12 MR. SNELL: Objection, form.</p> <p>13 THE REPORTER: No, I don't.</p> <p>14 MR. KUNTZ: Okay. No more questions.</p> <p>15 RECROSS-EXAMINATION</p> <p>16 BY MR. SNELL:</p> <p>17 Q. In your opinion, is the mechanical and</p> <p>18 laser cut mesh the same regardless of the way you cut</p> <p>19 it?</p> <p>20 A. Yes.</p> <p>21 Q. And is that why you cite to 11- and 17-year</p> <p>22 data for the TTV devices?</p> <p>23 A. Yes.</p> <p>24 Q. And if you look at your expert report--I'm</p> <p>25 glad Mr. Kuntz brought this up--you actually list the</p>

Michael P. Woods, M.D.

<p style="text-align: center;">Page 254</p> <p>1 chronology of different data on the TVT devices, 2 don't you?</p> <p>3 A. Yes.</p> <p>4 Q. And, actually, can you tell Mr. Kuntz, on 5 Page 39, whether the older studies and the 6 longer-term mechanical cut mesh, whether those rates 7 are any different than the newer studies or are they 8 the same?</p> <p>9 A. That's --</p> <p>10 Q. Can you answer my question, first: Are 11 they the same or are they different?</p> <p>12 A. Yes, they are.</p> <p>13 Q. "Yes, they are" what?</p> <p>14 A. They are the same.</p> <p>15 Q. All right. And what is the significance of 16 that to you in the question of whether it matters 17 clinically if their mesh is mechanical or laser cut?</p> <p>18 A. It does not matter clinically.</p> <p>19 Q. And from 1999 until 2007, every single TVT 20 mesh Retropubic device that you implanted, were those 21 mechanical cut or laser cut?</p> <p>22 A. Mechanical cut.</p> <p>23 Q. And since 2008, have you implanted both?</p> <p>24 A. Yes.</p> <p>25 Q. All right. And I think you told Mr. Kuntz</p>	<p style="text-align: center;">Page 256</p> <p>1 C-E-R-T-I-F-I-C-A-T-E 2 STATE OF NEBRASKA ) 3 ) ss. 4 COUNTY OF OTOE ) 5 I, Sondra W. Petersen, RMR, CRR, CSR(IA), 6 and General Notary Public in and for the State of 7 Nebraska, do hereby certify that MICHAEL P. WOODS, 8 M.D. was by me duly sworn to tell the truth, the 9 whole truth, and nothing but the truth; that the 10 deposition as above set forth was reduced to writing by me.</p> <p>11 That the within and foregoing pages were 12 taken by me at the time and place herein specified 13 and in accordance with the within stipulations; that 14 the foregoing deposition is a true and accurate 15 reflection of the proceedings taken in the above 16 case.</p> <p>17 That I am not counsel, attorney, or 18 relative of either party or otherwise interested in 19 the event of this suit.</p> <p>20 IN TESTIMONY WHEREOF, I place my hand and 21 notarial seal this 6th day of October, 2015.</p> <p>22</p> <hr/> <p>23 SONDRA W. PETERSEN, RMR, CRR, CSR 24 GENERAL NOTARY PUBLIC 25</p>
<p style="text-align: center;">Page 255</p> <p>1 you could see the difference, you could tell the 2 difference because you worked with a mesh right up 3 close when you're considering implanting it?</p> <p>4 A. It's in my hands and I am looking at it.</p> <p>5 Q. And did you ascertain any difference 6 whatsoever in the implantation of a laser cut versus 7 a mechanical cut mesh?</p> <p>8 A. No.</p> <p>9 Q. And I think you told me that they're both 10 covered and encased by a sheath, right?</p> <p>11 A. Yes.</p> <p>12 Q. And have you assessed or found any 13 difference in complications in those meshes?</p> <p>14 A. No.</p> <p>15 MR. SNELL: No further questions.</p> <p>16 (4:21 p.m. - Adjournment.)</p> <p>17 § § §</p> <p>18 (Signature reserved.)</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: center;">Page 257</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition 4 over carefully and make any necessary 5 corrections. You should state the reason 6 in the appropriate space on the errata 7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign 9 the errata sheet and date it. It will be 10 attached to your deposition.</p> <p>11 It is imperative that you 12 return the original errata sheet to the 13 depoing attorney within thirty (30) days 14 of receipt of the deposition transcript 15 by you. If you fail to do so, the 16 deposition transcript may be deemed to be 17 accurate and may be used in court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

Michael P. Woods, M.D.

<p style="text-align: center;">Page 258</p> <p>1       -----  2       ERRATA  3       -----  4       PAGE LINE CHANGE  5       REASON: _____  6       REASON: _____  7       REASON: _____  8       REASON: _____  9       REASON: _____  10      REASON: _____  11      REASON: _____  12      REASON: _____  13      REASON: _____  14      REASON: _____  15      REASON: _____  16      REASON: _____  17      REASON: _____  18      REASON: _____  19      REASON: _____  20      REASON: _____  21      REASON: _____  22      REASON: _____  23      REASON: _____  24      REASON: _____  25      REASON: _____</p>	<p style="text-align: center;">Page 260</p> <p>1       LAWYER'S NOTES  2       PAGE LINE  3       _____  4       _____  5       _____  6       _____  7       _____  8       _____  9       _____  10      _____  11      _____  12      _____  13      _____  14      _____  15      _____  16      _____  17      _____  18      _____  19      _____  20      _____  21      _____  22      _____  23      _____  24      _____  25      _____</p>
<p style="margin-top: 10px;">Page 259</p> <p>1       ACKNOWLEDGMENT OF DEPONENT  2  3       I, _____, do  4       hereby certify that I have read the  5       foregoing pages, and that the same  6       is a correct transcription of the answers  7       given by me to the questions therein  8       propounded, except for the corrections or  9       changes in form or substance, if any,  10      noted in the attached Errata Sheet.</p> <p>11  12  13  14  15      Subscribed and sworn  16      to before me this  17      _____ day of _____, 20_____.  18      My commission expires: _____  19  20  21  22  23  24  25      Notary Public</p>	

66 (Pages 258 to 260)

Golkow Technologies, Inc. - 1.877.370.DEPS

A	accounts	35:21 37:3	1:10,11,11,12	74:2 76:13
<b>a11</b> 9:12 10:19	<b>accumulated</b>	<b>ago</b> 20:9 78:20	1:12,13,14,14	88:9 95:24
<b>a16</b> 6:4 11:7	205:14	197:11	1:15,16,16,17	115:21,24
12:25 199:23	<b>accurate</b> 77:13	<b>agree</b> 29:13	1:18,19,19,20	117:18,25
<b>aagl</b> 131:11	100:3 144:22	32:17,20 38:12	1:20 2:2,2,3,3	118:1,4 120:3
<b>ab</b> 126:5	149:2,4 256:14	38:15 45:10	2:4,4,5,5,6,7,8	120:17 121:6
<b>abbrevo</b> 28:9	257:17	86:4,15,20	2:9,10,11,12	121:10 122:20
35:18 102:13	<b>acknowledged</b>	94:14 108:7,9	2:12,13,13,14	123:21,23
102:15 106:17	81:25	108:11,18	2:15,15,16,16	124:22 147:7,9
106:19 108:3	<b>acknowledgm...</b>	112:11,22	2:17,18,19,19	158:24 168:6
150:4 154:23	259:1	120:3 129:21	2:20,20,21,22	183:9
<b>abdominal</b> 10:2	<b>acog</b> 131:12	135:14 140:8	2:22,23,23,24	<b>amounts</b> 121:14
166:20 167:11	<b>acogs</b> 92:21,23	150:22 151:19	2:24 201:10	<b>ams</b> 63:13,16,19
187:20 234:2,2	<b>acquaintance</b>	152:1,5,14,16	<b>align</b> 85:5	134:16,25
<b>abide</b> 96:1	204:22	153:12,16	<b>alive</b> 33:14	135:4 136:23
<b>ability</b> 49:19	<b>actions</b> 81:1	154:18 156:13	<b>allday</b> 51:13	137:3 149:25
52:8 117:1	<b>actively</b> 16:15	156:20 157:12	<b>alleged</b> 233:8	150:1 241:24
156:14 157:1	<b>actual</b> 73:8 74:8	158:12 159:7	<b>alleviated</b>	248:2
<b>able</b> 10:7 61:15	74:16 93:5	166:2 167:19	230:19	<b>analyses</b> 213:17
70:14 123:22	105:20 164:9	168:5 169:10	<b>alloplastic</b>	<b>analysis</b> 91:17
133:16 160:10	212:9	177:2 178:17	190:13	100:1,5,10,13
165:24 175:15	<b>acute</b> 9:20 10:1	179:6 235:23	<b>allow</b> 193:3	100:15 160:19
214:22 237:19	<b>add</b> 13:10,11,16	<b>agreed</b> 184:22	245:7	161:23 162:5
<b>abroad</b> 235:8	137:11,25	<b>agreement</b> 5:16	<b>allowed</b> 14:21	163:12,16,23
<b>absolute</b> 164:22	<b>addition</b> 137:25	5:17,18,19,20	103:5 122:22	164:11 171:1
<b>absolutely</b> 15:18	138:9 231:22	5:21 57:23	133:8	236:3
15:24 32:5,13	<b>adequate</b> 142:9	58:5 63:10,21	<b>allows</b> 43:7	<b>anatomy</b> 159:1
38:17 133:1	<b>adequately</b>	64:4 96:23	194:8 245:5	159:4
135:11 165:12	242:10	115:18 117:21	<b>alternative</b>	<b>anchoring</b> 107:2
192:22 209:11	<b>adhesion</b> 31:22	119:11 120:6	150:2 229:11	108:5 241:23
215:3 240:20	<b>adjournment</b>	134:6	<b>altis</b> 28:10,14	241:25
<b>absorbable</b>	255:16	<b>agreements</b>	62:25	<b>anchors</b> 9:14,22
180:14 185:20	<b>adjust</b> 156:14	56:24 60:11	<b>american</b> 9:1	200:12
186:1,7,11	157:1	64:13 133:24	161:3 191:18	<b>anecdotal</b> 14:21
<b>abstract</b> 145:14	<b>adjusting</b>	<b>ahead</b> 13:5 24:4	<b>amid</b> 18:11	234:22 235:4
243:24	155:14 159:8	28:3 33:7 39:9	30:10,16,21,23	<b>anesthesia</b> 18:2
<b>acceptable</b>	<b>admit</b> 26:14	101:8 104:20	31:3,8,12,16	155:20,21
140:24 196:4	<b>advising</b> 250:21	137:24 169:17	42:14 167:22	<b>anesthetic</b> 18:5
<b>access</b> 74:4	<b>advisory</b> 132:6	173:12 185:23	168:1 184:16	168:14 243:10
105:15	<b>advocate</b> 129:21	187:4 215:18	184:22 191:13	243:25 244:4,7
<b>accountable</b>	129:25	225:8 228:1,8	191:20 208:24	<b>angles</b> 248:13
187:2	<b>affect</b> 14:22	<b>ahold</b> 81:19,25	231:4,13	<b>animal</b> 72:2
<b>accountant</b>	73:12	<b>airfare</b> 88:12	244:15,21,25	187:13
119:10	<b>age</b> 171:3	<b>airport</b> 226:14	245:4	<b>annual</b> 131:12
<b>accounting</b>	202:20	<b>ajog</b> 5:24	<b>amount</b> 11:15	<b>answer</b> 14:13
118:17	<b>agents</b> 28:11	<b>al</b> 1:7,7,8,8,9,10	17:16 26:14	15:4,7,7 19:1

Michael P. Woods, M.D.

Page 262

25:17 38:25	154:19 198:5	175:12 185:25	217:8 220:1,24	<b>attended</b> 24:9
39:9,17 40:5	<b>apply</b> 11:13	<b>articlesand</b> 70:5	221:13,21	123:1 129:16
42:2 46:18,20	82:11 154:21	<b>ascertain</b> 221:1	234:24 237:19	131:2,24
49:19 51:22	154:23 235:7	255:5	244:20	<b>attention</b> 36:13
52:4,7,10	251:12 252:23	<b>aside</b> 124:13	<b>assessed</b> 207:6	39:15 55:5
55:14 74:19	<b>approach</b>	125:2,9 142:2	210:15 213:24	121:12
97:12 111:4	141:24 188:25	185:18	232:7 233:17	<b>attorney</b> 256:17
117:1 121:11	198:23	<b>asked</b> 14:9,23	237:6,13 238:1	257:13
122:23 126:6	<b>approached</b>	24:10,19,19,25	255:12	<b>attorneys</b> 79:15
126:10 170:11	42:18 84:11	31:6 53:5	<b>assessing</b> 141:2	<b>aua</b> 8:20 10:18
171:13 172:2	135:4	55:25 61:19	141:4 192:18	11:3,5 160:22
180:25 254:10	<b>appropriate</b>	68:2 71:22	202:24 209:4	168:2 193:5
<b>answered</b> 39:3	44:24 45:1	73:13 78:2	214:2 215:1	199:23 231:22
104:19 153:15	257:6	89:5 92:4	216:7 228:25	<b>audubon</b> 23:5
153:22 181:5	<b>appropriately</b>	97:16 104:18	236:10 245:22	36:20
221:4,6,8	108:12	133:23 134:1	245:23	<b>augs</b> 92:24
<b>answering</b> 21:15	<b>approved</b> 103:3	135:22,25	<b>assessment</b>	150:16,18,22
21:15	103:17	137:21 150:7	188:4 201:14	150:24 151:14
<b>answers</b> 42:1,2	<b>approximately</b>	153:14,21	206:21 217:21	152:8,8,10
259:4	144:21 145:3	166:12,13,20	229:8 241:17	154:18 168:3
<b>antioxidant</b>	145:20 244:5	172:13,15	241:18	184:21 191:19
176:5	<b>area</b> 38:5 41:3	181:4 182:8,8	<b>associated</b> 9:18	<b>august</b> 63:22,23
<b>antioxidants</b>	97:24 98:1,2	182:9 187:11	10:5,10,22	<b>australia</b> 242:1
176:2	197:18 222:4	188:6,9 210:20	11:23 114:15	<b>austrian</b> 174:5
<b>anybody</b> 37:8	<b>areas</b> 143:4	218:1 221:3	228:14 232:5	174:23
109:8 110:22	<b>arent</b> 72:11	222:18 225:24	<b>association</b> 9:1	<b>author</b> 133:19
143:17	<b>argumentative</b>	226:2 228:22	87:9,11 191:19	167:9,15,15
<b>anymore</b> 16:15	252:17	234:4 241:9	<b>associations</b>	201:9 229:1
83:19 146:5	<b>aralone</b> 247:8	242:18	161:3	<b>authority</b> 87:17
<b>anyway</b> 117:14	<b>arm</b> 239:13,13	<b>asking</b> 9:16	<b>assume</b> 118:4,5	<b>authors</b> 30:3,6
<b>apologize</b> 17:15	239:17	11:16 24:24	126:10 235:20	150:9 177:2,7
26:13 53:5	<b>armamentari...</b>	140:24 163:24	<b>assumed</b> 54:8	177:14 178:7
56:12 241:7	128:18	185:16	186:19	178:11 192:2
<b>appear</b> 113:2	<b>arms</b> 210:11	<b>asks</b> 11:21	<b>assumption</b>	217:8 227:22
<b>appearances</b> 4:1	<b>arose</b> 85:4	170:18	102:18 111:18	<b>autologous</b> 8:17
5:3	<b>arteriography</b>	<b>aspect</b> 31:4	<b>asymptomatic</b>	8:18,19 9:2,14
<b>appendix</b> 6:4	138:16,22	84:21 97:14	177:1 224:17	12:14 30:15
9:10,12 10:18	<b>article</b> 5:24 6:6	209:9 236:11	<b>atkins</b> 1:16	138:13 168:11
11:5,6 12:24	6:8,10,11	<b>aspects</b> 241:11	<b>attach</b> 186:10,11	199:6 200:2,7
12:25 199:23	68:25,25 71:14	<b>assess</b> 150:3	<b>attached</b> 72:7	200:12,17
<b>application</b>	75:8 85:20	194:15,19,22	257:10 259:6	216:18,24
167:6 182:1,3	175:17 179:3	195:23 196:22	<b>attachment</b> 67:2	219:6 220:8
190:5 206:10	<b>articles</b> 69:9,13	197:2,6,14	<b>attempt</b> 56:23	221:22 245:24
236:15	69:14,15 70:2	203:13,18	<b>attempting</b>	246:2,6
<b>applied</b> 150:20	70:8,9 73:9,10	205:3,5,8	133:9	<b>available</b> 15:23
<b>applies</b> 150:17	172:20 173:8	208:9 216:2	<b>attend</b> 131:16	27:20 82:23

Michael P. Woods, M.D.

Page 263

84:22 120:4	55:1 66:23	104:7,17,21	193:2 196:18	231:6 248:16
121:20 130:9	70:11,21	106:10 110:8	226:20	<b>bladder</b> 9:20
130:21 148:14	219:18	114:18 115:5	<b>better</b> 29:22	10:1,16 11:8,8
172:16 192:25	<b>baltimore</b>	117:23 119:13	40:24 41:14,22	11:10,13 12:3
193:2 194:13	125:25	120:8 121:19	42:5 59:8	12:5 55:18
195:4 196:19	<b>bar</b> 104:1	122:6 127:10	84:10,16 93:10	217:17 224:15
249:10	<b>barcelona</b>	133:11 136:24	141:7 167:24	<b>blaivas</b> 49:17
<b>avenue</b> 4:5	126:19,20	145:7 149:11	204:12 207:18	50:13 233:12
<b>awake</b> 155:18	<b>barr</b> 2:5	149:13,19	216:20,21	<b>blanket</b> 46:14
<b>aware</b> 15:6,11	<b>base</b> 98:4,5	150:12,16	217:6 229:12	64:1 155:9
18:17,23 19:3	101:4	153:23 154:8	<b>beyond</b> 95:23	<b>blanking</b> 89:19
34:15 101:14	<b>baseball</b> 214:18	156:7,9 157:14	96:16 101:18	<b>bleeding</b> 9:20,23
109:21 112:8	<b>based</b> 158:25	157:17,21	153:24 178:25	9:24 10:1
112:21 114:9	<b>baseline</b> 104:22	158:15 159:3	<b>big</b> 129:21,24	11:25
114:17 129:20	<b>basement</b> 81:10	164:21 167:2,9	142:24 208:18	<b>block</b> 149:9
135:5,23	<b>basis</b> 105:1	167:22 169:6	245:3	<b>blocks</b> 139:13
169:25 171:20	218:25	169:23 170:7	<b>bigger</b> 216:19	<b>blood</b> 194:9
175:16 180:13	<b>bathroom</b> 225:7	170:14 171:7	<b>bill</b> 53:6 54:25	245:6,9
182:5 203:3	<b>batke</b> 186:16	171:10,15	83:3,6	<b>bluffs</b> 22:4,6
229:5 235:12	<b>bearing</b> 77:15	175:2 176:12	<b>billing</b> 60:9	<b>board</b> 51:1 55:7
235:17	<b>beds</b> 93:8	178:20 179:9	147:14,18,20	82:17,18
	<b>began</b> 218:18,24	179:16 185:19	148:13	150:17 187:1
	<b>B</b>	187:13 189:24	<b>biocompatibil...</b>	<b>boards</b> 132:6
<b>b</b> 4:10 67:3,11		201:5 212:19	167:25 193:23	<b>bodies</b> 202:19
<b>back</b> 55:19		212:25 214:23	194:3,12,15,24	<b>body</b> 73:19
58:11 89:8,11	<b>believe</b> 9:17	214:25 218:5	104:16 170:10	
96:19 109:1	10:4,9,14 11:2	219:21 227:3	171:3,11	
115:8 118:24	13:24 17:13	233:17 249:14	197:16 199:8,9	
118:25 119:25	19:13 23:25	253:4	207:10 209:1	
124:18 137:10	24:15 26:2	<b>believed</b> 32:1	233:5 238:12	207:10 209:1
138:5 144:23	27:4,16,19	<b>believei</b> 101:21	238:22,24	211:16 213:13
146:14,18,20	29:3 32:3,8	<b>bell</b> 100:17	240:11 244:15	245:6
153:4 154:12	34:2 38:17,18	<b>bellevue</b> 58:23	<b>biocompatible</b>	<b>bone</b> 9:14,22
155:19 208:24	40:14 42:19	59:13,15	195:10 206:23	200:12
216:15 217:7	43:1 44:22,24	<b>bench</b> 91:8	207:3	<b>book</b> 91:4
224:3,3 237:11	45:3,16 46:3	<b>benchtop</b> 27:8	<b>biomaterials</b>	<b>booth</b> 131:20,22
243:11,15,16	51:19 53:13	98:13 212:7,19	92:15,17	<b>boris</b> 186:16
243:20 245:2	55:5 57:13	212:20,25	196:11	<b>bottom</b> 117:15
250:18 252:14	62:11,20 63:21	<b>bennett</b> 2:24	<b>biomechanical</b>	<b>bottomofther...</b>
253:5,9	64:5,6,18	<b>best</b> 25:12,13	194:2	109:22
<b>backup</b> 216:17	78:17 79:13	49:19 52:8,11	<b>biomedical</b>	<b>bottomup</b>
<b>bacterial</b> 230:18	82:4 86:22,22	70:3 84:18	94:12	207:22
230:21	87:10,11 89:14	117:1 119:18	<b>bit</b> 41:24 88:20	<b>bovine</b> 31:1
<b>bad</b> 208:2	93:19 98:20	136:19 172:16	120:1 138:25	<b>bowel</b> 9:20 12:2
<b>balanced</b> 59:5	99:19 101:4,12	173:2,4,20	158:18 167:16	<b>boxes</b> 62:20
<b>ballpark</b> 54:23	101:17 102:20	184:24,24	171:2 204:11	<b>boy</b> 250:2
			221:23 230:14	<b>break</b> 26:20,25

Michael P. Woods, M.D.

Page 264

48:3 54:5 66:7	200:17 216:23	231:6	173:1 188:15	138:10 171:2
66:13 76:10	217:4 220:8	<b>called</b> 3:5 19:8	226:14 235:4	199:15
101:25 137:10	221:22 243:21	64:19 180:14	244:17 246:2	<b>changes</b> 137:23
137:22 144:15	245:24 246:1,6	210:15 234:22	256:16	259:5
174:10 175:1	<b>burches</b> 140:2,6	<b>calls</b> 14:2 18:20	<b>cases</b> 1:6 42:3	<b>changing</b> 207:5
224:12 225:7	200:3 216:15	52:24 129:18	78:10,21 79:18	<b>chapter</b> 190:12
<b>breakdown</b>	219:6	<b>cammu</b> 185:7,9	80:7 118:5	<b>characteristics</b>
145:15 161:13	<b>burchs</b> 222:2	185:12 186:1	46:6	46:6
<b>breaking</b> 137:6	<b>burgoyne</b> 2:23	<b>canceled</b> 182:14	<b>charge</b> 22:18,21	
<b>bremmer</b> 79:7	<b>burned</b> 231:16	183:1,4	55:3	
79:14	<b>burt</b> 4:10,13	<b>cant</b> 13:17 27:15	<b>charged</b> 173:19	
<b>bridging</b> 166:4	15:3 39:5	36:11 54:21	244:1	
166:18	52:16 105:18	70:9 100:15	<b>charleston</b> 1:2	
<b>briefcase</b> 151:5	187:4	117:24 157:10	<b>chart</b> 21:8	
<b>briefly</b> 74:21	<b>business</b> 59:19	164:9 170:4	101:23 102:5	
100:11 101:10	84:21 124:8	176:15 186:3	<b>chartis</b> 101:22	
<b>brigitte</b> 186:14	<b>busy</b> 54:7	<b>capacity</b> 166:16	<b>cheap</b> 250:6	
<b>bring</b> 48:21 49:4	<b>butler</b> 4:10,14	<b>caption</b> 2:1 5:2	<b>cheat</b> 53:21,23	
56:23 155:25	<b>butlersnow</b> 4:13	<b>car</b> 56:3	54:13,16	
156:3 243:23	4:17	<b>care</b> 25:12 32:1	<b>check</b> 61:2	
<b>bringing</b> 124:20	<b>buttress</b> 138:15	32:9,12,18,21	105:24 141:3	
<b>brittle</b> 175:21	<b>C</b>	38:10 44:23	<b>checked</b> 75:13	
176:11,12,14	<b>c</b> 7:2 67:2	45:11,16,21,22	<b>checking</b> 226:15	
176:17	<b>cab</b> 226:15	46:3 130:19	<b>checks</b> 247:5	
<b>broad</b> 20:2	<b>cadaver</b> 102:10	187:2	<b>chemical</b> 90:11	
166:21	105:20 107:13	<b>career</b> 16:10	90:13 171:1	
<b>broke</b> 176:17	107:14 108:1	140:3 206:17	209:10	
193:19	127:8,14 183:6	218:9 219:15	<b>chemistry</b> 91:6	
<b>broken</b> 175:23	242:15	222:2 245:15	<b>cheshire</b> 2:22	
175:24	<b>cadaveric</b>	<b>carefully</b> 257:4	<b>chicago</b> 50:14	
<b>brought</b> 48:18	248:15	<b>carolyn</b> 76:25	91:3 123:7	
49:2 79:11	<b>calendar</b> 58:7	77:3,4,6	<b>choice</b> 42:5	
126:23 164:7	<b>calibration</b>	<b>cartmell</b> 4:5	<b>chose</b> 248:13	
253:25	158:12	<b>case</b> 5:2 7:14	<b>chronic</b> 143:2,3	
<b>brubaker</b> 85:20	<b>california</b>	34:8,17 43:11	143:6 164:15	
85:22	123:13,17	49:15 50:18,21	164:19	
<b>bulking</b> 28:11	125:14 126:2	51:9 55:17,18	<b>chronology</b>	
35:21	127:11	55:21,23 56:1	254:1	
<b>bundle</b> 99:15	<b>call</b> 18:13 36:4	56:2,3 64:17	<b>chunk</b> 66:19	
<b>bunman</b> 78:13	52:25 54:13	64:21 68:7	<b>circle</b> 3:11	
78:16,16	81:14 82:16	75:22 76:25	<b>circumstances</b>	
<b>burch</b> 12:14	92:17 93:14	77:3,5,16 78:6	139:18	
51:7 89:9 90:3	108:21,25	78:7,19 80:15	<b>cite</b> 164:7	
139:21,24,25	136:13 139:7	80:18 81:7,21	185:19 186:3	
140:9 161:15	142:6 176:19	100:10 172:12	222:20 223:3	
163:4 200:8,10		172:23,25	<b>changed</b> 84:19	253:21

Michael P. Woods, M.D.

Page 265

<b>cited</b> 70:2,18 71:16 73:19 74:14 75:9 76:4,12 236:2 248:17 <b>cities</b> 123:1 126:25 127:8 <b>city</b> 4:6 55:24 89:13 123:2 125:19 126:17 127:11 <b>civil</b> 3:7 <b>claims</b> 233:10 233:15 250:3 <b>clamp</b> 94:22 95:2,5 <b>clamps</b> 212:3 <b>clarify</b> 137:13 <b>clarifying</b> 114:7 <b>class</b> 91:1 207:5 207:6 <b>classic</b> 36:5,9 40:19 41:6 <b>classical</b> 191:6 195:5 <b>classification</b> 18:11 30:10,16 30:21,23 31:3 31:8,12,16 42:14 167:23 168:1 184:16 184:23 191:13 191:20 193:16 208:25 231:4 231:16 245:5 <b>clean</b> 145:2 <b>clear</b> 20:11 144:17 185:18 211:1 <b>clearance</b> 242:3 <b>clinical</b> 35:20 42:5 59:7 62:8 83:23 84:2 101:15 111:12 111:14 131:12 151:21 170:2,6	172:1,5,21 173:9 177:9,13 180:9 194:14 196:2,3 203:10 205:4,18,22 213:8 235:24 236:11 <b>clinically</b> 171:4 175:3,13 202:14 213:19 214:5 235:21 254:17,18 <b>clinician</b> 214:15 <b>clinics</b> 59:14 186:25 <b>close</b> 84:12,14 219:18 255:3 <b>closed</b> 84:1 85:3 <b>closely</b> 76:2 148:21 <b>coauthors</b> 80:25 <b>cochrane</b> 5:23 141:19 191:25 192:11,13,14 193:2,4,14,15 195:7 207:20 <b>cohort</b> 109:24 189:20 <b>collaboration</b> 5:23 <b>collagen</b> 194:6 194:10 <b>collapse</b> 166:3 166:17 167:4 232:22 233:3 <b>colleagues</b> 29:19 29:24 171:20 <b>colony</b> 4:15 <b>coloplast</b> 28:16 93:16 97:7 98:8 105:15 132:3 133:5 212:1 <b>companyspon...</b> 131:2 <b>compare</b> 200:7 243:20 245:23	221:22 <b>colposuspensi...</b> 8:14 <b>colpotomizer</b> 242:2 <b>com</b> 1:25 4:7,7 4:13,17 <b>combined</b> 144:21 <b>come</b> 11:21 83:4 146:7,12,14 154:7 204:20 <b>comes</b> 102:7 109:25 127:10 176:9 <b>comfort</b> 231:6 <b>comfortable</b> 36:7 231:7 <b>coming</b> 29:1 99:7 106:17 148:19 <b>comment</b> 188:9 <b>commission</b> 259:16 <b>committee</b> 92:21 92:22,23,24 <b>common</b> 86:10 191:11 <b>communicate</b> 68:11,12 <b>community</b> 23:5 23:6 36:20,22 83:22 <b>companies</b> 62:23 83:17 <b>company</b> 42:18 58:25 78:2 <b>colony</b> 4:15 <b>coloplast</b> 28:16 93:16 97:7 98:8 105:15 132:3 133:5 212:1 <b>companyspon...</b> 131:2 <b>compare</b> 200:7 243:20 245:23	<b>compared</b> 36:9 102:14 198:17 208:22 221:21 229:3 234:16 <b>comparing</b> 110:22 111:8 222:1 <b>comparison</b> 5:15 8:22 102:9 <b>compatibility</b> 236:10 <b>compatible</b> 197:15 <b>compensated</b> 137:17 226:7 <b>complained</b> 162:23 <b>complete</b> 171:23 <b>completed</b> 82:8 <b>completely</b> 168:12,18 177:1 <b>complexity</b> 96:14 <b>compliance</b> 45:6 81:4,22 <b>complication</b> 6:4 9:12 10:10 21:22,24 161:2 165:6 174:15 197:18 199:23 208:11 211:23 219:25 221:16 221:24 238:8 238:19 <b>complications</b> 7:18 8:9 9:17 10:4,13,22 34:6,8,11,14 47:18,21,24 86:21 109:18 110:4,14,22 111:9,13 114:14,19,22 140:24 142:15	142:19,21 162:10 170:6 173:10 174:7 180:12 193:24 196:3,6 197:24 198:16 199:13 206:7 208:21 215:15 216:1,8 216:18 217:24 220:2,13,15,19 220:22 221:2 224:7 229:2 231:8 255:13 <b>component</b> 24:25 <b>components</b> 99:11 230:2,6 <b>compound</b> 13:4 180:4 <b>computer</b> 60:20 61:2,18 81:14 89:22,23 <b>concern</b> 184:21 190:22 <b>concerned</b> 230:17 231:9 <b>concerns</b> 31:15 157:1 171:21 <b>concluding</b> 232:1 <b>conclusion</b> 214:22 <b>condense</b> 70:15 <b>conflict</b> 133:19 <b>confused</b> 17:16 <b>conjecture</b> 99:20 176:15 <b>connective</b> 46:7 194:4 <b>conscience</b> 133:16 <b>consensus</b> 158:24 <b>consent</b> 133:2 <b>consider</b> 15:12 15:15 46:11
--	---	---	---	---

Michael P. Woods, M.D.

Page 266

92:17 97:23 128:10,17 153:5,6 <b>considered</b> 134:11,12 223:15 237:2 <b>considering</b> 202:19 255:3 <b>consistency</b> 214:13 <b>consistent</b> 119:13 200:21 200:25 202:10 205:17,21 213:2 240:22 240:25 241:5,6 <b>constantly</b> 228:19 <b>construction</b> 18:14,21 19:9 <b>consult</b> 57:18,21 57:24 63:24 249:15 <b>consultant</b> 56:20 57:6,11 60:1 64:22 94:18 130:13 131:9 133:5 135:4 226:8 247:4 <b>consulted</b> 35:9 92:20 95:4 241:12,22,24 242:1 250:10 <b>consulting</b> 5:16 5:17,18,19,20 5:21 56:24 57:22 58:4 60:4,11 63:9 63:19,20,21 64:1,3,7,10,12 68:12 96:7,22 98:23 115:3,18 117:21 119:11 119:14 120:6 124:25 133:24 226:1,25 227:4	<b>contact</b> 47:10 64:16 80:12 81:10,16 118:11 156:3 159:5 <b>contains</b> 176:5 <b>contamination</b> 230:18,21 <b>contention</b> 203:7 <b>contesting</b> 189:10 <b>continence</b> 47:25 203:25 <b>continuation</b> 47:13 <b>continue</b> 92:8 225:17 <b>continued</b> 2:1 47:10 <b>continues</b> 155:5 215:14 216:10 <b>continuing</b> 206:6 <b>continuous</b> 51:5 <b>contract</b> 115:24 116:14 117:18 120:4,17 121:7 121:10,21 122:5,11,20 134:10,12 225:13,16,20 225:21 <b>contracted</b> 88:9 <b>contracts</b> 134:4 <b>contrary</b> 157:24 <b>contrast</b> 138:13 138:20 <b>control</b> 149:14 205:4 214:21 222:15 236:20 240:4 <b>controlled</b> 74:6 109:23 111:11 141:18 164:14 165:4 173:3,22	176:22 189:18 195:15 222:7 222:10 <b>convince</b> 177:17 <b>cook</b> 2:7 <b>cooperated</b> 81:24 <b>coordinating</b> 125:10 <b>copied</b> 120:2 <b>copies</b> 80:3 242:16 <b>copromoted</b> 130:11 <b>copy</b> 17:1 54:21 56:16 65:12 <b>corporate</b> 44:20 84:13 <b>corporation</b> 58:21,22 <b>correct</b> 9:3 12:8 16:21 32:2,18 35:4 42:22,23 43:18,20,25 44:1,13 46:23 46:24 53:17 56:21 65:14,22 66:12 68:13 72:7 73:6,16 73:17,25 74:9 74:10 77:17 85:24,25 86:21 87:3,6 88:23 89:8 90:3 93:13 98:1 100:7 102:6 104:16 106:22 107:16,17,19 107:20,22,23 107:25 108:1 114:19 115:6,7	115:19,20,22 116:1 117:19 117:20 119:5 120:5,18 121:8 122:5 123:24 127:14,15 131:3 140:10 142:4 148:1,3 148:20 163:20 165:21 171:22 173:3 174:18 174:21 177:20 177:21 178:8 181:3 183:12 184:2 187:14 189:2 217:1 218:3 239:5,14 242:25 246:20 246:25 247:19 249:5,6,9 259:4 <b>correction</b> 137:24 138:19 <b>corrections</b> 257:5,7 259:5 <b>correctly</b> 227:5 <b>correlated</b> 177:3 177:23 <b>correlates</b> 210:4 <b>cough</b> 155:17,20 158:17 <b>coughing</b> 107:19 <b>couldnt</b> 47:20 60:19 81:25 92:13 107:15 107:18,21,24 <b>council</b> 22:4,6 <b>counsel</b> 7:24 25:11 50:18 51:9 53:2,16 61:23 62:4,18 62:21 67:18,19 69:13 75:1,1 113:9,22 192:5 192:25 196:19 216:23 218:1	228:22 241:9 256:17 <b>counseled</b> 204:2 <b>counseling</b> 215:20 <b>country</b> 124:15 <b>county</b> 23:3 256:3 <b>couple</b> 16:11 54:11 97:18 130:10 155:18 174:2 206:18 246:16 <b>course</b> 51:2 58:12 239:11 239:16 <b>courses</b> 127:17 <b>court</b> 1:1 257:17 <b>courts</b> 3:7 <b>cover</b> 122:14 187:9 <b>covered</b> 227:13 255:10 <b>cracking</b> 170:23 <b>crawford</b> 23:3 <b>create</b> 70:5 <b>created</b> 95:10 <b>credence</b> 73:12 109:5 <b>credé</b> 155:22 158:16 <b>croatia</b> 101:3 <b>crosscountry</b> 60:21 <b>crossexaminat...</b> 5:8 187:6 <b>crossexamine</b> 117:7 <b>crr</b> 3:9 256:4,23 <b>csr</b> 3:9 256:4,23 <b>curbside</b> 61:2 <b>cure</b> 201:22 202:1 207:18 223:10,11 238:3 <b>curl</b> 108:13
--	---	---	---	---

Michael P. Woods, M.D.

Page 267

<b>curling</b> 108:14 232:14	214:7 215:7,8 215:10,18	170:1,15 173:14,17,23	<b>death</b> 13:7 33:18 33:21	171:11 235:15 235:24
<b>current</b> 35:15 64:3 86:24 96:17 139:1,2 191:13 194:14	227:24 228:17 228:21 229:3,3 229:12,13 236:16 239:22	173:25 174:8 178:12 187:17 187:19,22 193:2 196:19	<b>debodinance</b> 154:14	<b>degraded</b> 175:11 176:13
<b>currently</b> 36:9 36:15,17 63:9 223:15	248:21,21,23 249:5,5 251:5 251:12,14,19	202:10 204:6,8 209:24 211:20 211:21 215:21	<b>december</b> 115:19	176:18,20 235:21
<b>customer</b> 134:20	252:3,12,15,23	217:3 220:25	<b>decide</b> 85:2	<b>degrades</b> 170:5
<b>customize</b> 109:14	253:6,9,18,18 254:6,17,21,21 254:22 255:6,7	222:1,15,25 231:18 234:16 236:2 249:2	<b>decided</b> 84:13 161:24	170:8 171:8 203:1,8
<b>cut</b> 7:19 8:10 19:12,13,18,18 19:24 20:15,19 20:20 21:4,4,9 21:9,24,25 22:8,9,15 23:16,17,21,21 23:23 24:5,12 24:15 25:2,20 25:21 26:1,1 27:6,7,13,15 27:17,24,25 38:13,16,19,21 38:23 39:13,15 39:24 40:3,8 40:13 42:8,8 109:2,3,12,12 109:13 110:5,5 110:10,23,23 111:9,10,16,17 111:22,22 112:6,6,17,17 141:25 142:1 149:17,18,20 149:22,23 150:8 155:16 159:16,16,23 160:6,7 165:20 165:20 166:14 167:3 175:25 187:18 195:6 210:21,21 211:4,20,22 213:11,12,20	<b>cutting</b> 210:22 211:5,6,14 <b>cv</b> 49:2 57:24 59:25 85:19 115:6,10 116:22 117:7 186:22,23 <b>cycle</b> 226:11	250:12,17 251:6,10,12,18 251:18,25 252:1,4,16,22 252:23 253:10 253:22 254:1	<b>decreasing</b> 239:10	<b>decreasing</b> 170:25
		<b>dataits</b> 70:4	<b>deemed</b> 257:16	<b>deliberate</b> 212:9
		<b>date</b> 17:13 41:2 95:13 102:25 119:14 155:7 257:9 259:8	<b>deep</b> 95:3	<b>delineate</b> 149:22
		<b>dated</b> 225:13	<b>defect</b> 141:25	<b>demonstrate</b> 195:19
		<b>dates</b> 123:22	<b>defectively</b> 189:11	<b>demonstrated</b> 206:23 207:13
		<b>david</b> 68:9,15	<b>defects</b> 233:8	<b>denise</b> 80:23
		<b>day</b> 52:15 53:14 55:11 137:16 163:10 194:19	245:16	<b>denison</b> 23:3,4
		196:16 221:11	<b>defendant</b> 55:21 78:11	<b>denver</b> 123:3
		<b>dan</b> 247:25,25 248:4 250:3	<b>defendants</b> 4:9	<b>department</b> 22:20 37:5,7
		<b>daniel</b> 1:10	<b>defense</b> 50:18 51:9 53:1,16 62:17 67:18,19	81:20 89:18
		<b>data</b> 15:22 27:12 27:14,17 29:1 31:22 47:6	69:13 75:1 113:9,22	<b>depend</b> 46:5,5 98:18 125:9 140:15
		68:1 70:7 72:2	<b>define</b> 175:5,6 175:10,13	<b>depending</b> 36:2 42:5
		74:2,18 81:16	<b>definite</b> 41:5	<b>depends</b> 19:16 108:20 170:25
		84:19 101:14	<b>definitely</b> 96:11	<b>deponent</b> 259:1
		111:19 134:9	<b>deformation</b> 108:14 212:9	<b>depos</b> 49:20
		148:21,21,25	124:10,13,24	<b>depose</b> 52:16
		149:19 150:8	125:2,6,7,9	<b>deposing</b> 52:18 257:13
		150:19,23	126:11,13	<b>deposition</b> 3:5 5:13 7:12 8:5,5
		152:21 153:17	127:11 257:13	50:2,5 53:20
		153:18 164:8	<b>dayton</b> 125:23 175:6,13	55:8,9 65:20
			<b>ddsa</b> 100:16 176:22 177:4	67:20 78:13,24
			<b>de</b> 217:18 202:11,15	79:9 116:25
			<b>dead</b> 33:8 232:24	181:2 252:24
			<b>degrade</b> 169:24 170:5,10,21	256:9,14 257:3 257:10,14,16
				<b>depositions</b> 3:8 49:14,16,25

Michael P. Woods, M.D.

Page 268

50:1,8,11 71:3 71:7 78:9 80:4 181:7 <b>deps</b> 1:25 <b>derive</b> 235:8 <b>des</b> 187:2 <b>describe</b> 93:11 168:5 170:25 208:20 <b>described</b> 168:22 <b>design</b> 15:20,25 47:9 93:2,4,10 93:10 94:15,21 94:25 96:10 98:25 99:4,13 108:5 112:21 167:2 169:20 180:11 187:21 188:18 208:21 208:22 209:3 209:16,18 210:13,18 215:2 217:22 229:24 230:2 230:11 240:12 240:14,19 241:2,10,13,17 242:11 248:13	<b>determines</b> 25:14 <b>determining</b> 193:6 <b>develop</b> 168:14 192:15 <b>developing</b> 130:14 180:17 180:22 242:2 <b>development</b> 68:16 95:4 108:2 180:18 209:11,16 <b>device</b> 7:19 10:22 12:10 13:2,21 14:1 18:10,21 33:2 39:16 41:5 62:23 63:5,12 78:2 93:16 94:4,7,20 95:1 95:9 96:7 97:4 98:8,9,13,18 98:19 99:3 104:11 108:3 114:8,12 118:7 118:7 128:15 130:10,12 133:10,15 <b>designed</b> 47:14 47:22 94:20 97:3,8 108:8 108:12,18 112:23 164:14 164:17,19 165:10 189:11 <b>designing</b> 95:21 96:7 98:9 <b>destroyed</b> 60:21 61:4,18 119:3 <b>detail</b> 70:25 <b>determinations</b> 149:1 <b>determine</b> 140:15 150:12 176:22 209:17	212:12 213:2 217:3,22 218:11,12 219:22 220:2 221:2,16,17 222:11,13,16 223:9 224:22 227:1 229:11 229:18,24 230:6,9,12 232:7,9 234:25 236:13,14,22 237:5 238:13 238:22 240:19 242:6,12 243:3 244:20 247:22 248:4 254:20 <b>devices</b> 16:9,21 17:6,9,10,21 19:11,24 20:4 20:15 44:5 93:13 94:15,18 95:7,21 114:6 154:2 207:21 218:24 219:14 229:9 241:11 241:12,16 253:22 254:1 <b>dictate</b> 22:7,11 23:7 <b>didnt</b> 18:19 20:5 154:20 155:11 155:12,13,15 155:17,19,24 156:1,7 157:9 158:21 159:4,9 159:18 164:16 173:21 179:8 189:5 194:16 195:10 196:23 196:24 197:14 197:15 200:6 201:7,15 203:19 206:2 207:15,17 210:1,14	<b>diego</b> 126:2 <b>dietz</b> 113:5 <b>difference</b> 19:20 20:19,24 21:4 21:18 25:25 26:3,4 27:6,24 28:5 77:23 110:4 111:8,13 111:16 112:3 213:19 214:6 238:5,9 255:1 255:2,5,13 <b>differences</b> 21:8 29:11 110:15 193:24 214:10 238:8 <b>different</b> 10:18 18:3 24:20 25:20 27:23 29:7 30:14 40:9 44:11 51:3 72:10 73:5,21 166:24 167:1,3 178:5 190:7 193:25 194:1 203:18 206:10,15 210:22 231:18 233:10 241:10 241:11 254:1,7 254:11 <b>differently</b> 32:5 <b>difficult</b> 125:13 168:6,22 176:24 216:16 234:5 242:20 243:5,12 <b>difficulties</b> 224:8,11,12 <b>difficulty</b> 169:4 169:7,9,19 243:20 <b>dillon</b> 1:11 <b>dinner</b> 123:19 <b>direct</b> 5:7 7:7 <b>directly</b> 143:9	<b>director</b> 186:25 <b>dirty</b> 250:7 <b>disagree</b> 121:24 122:2 152:1,6 152:14 153:20 159:25 160:5 160:12 166:8 166:10 172:14 177:11,14 178:14,18 234:4,9,12 242:20 <b>disclaimer</b> 131:8 <b>disclose</b> 132:21 133:6 <b>discomfort</b> 157:19 <b>discuss</b> 25:25 26:3 31:15 169:7 186:1 190:15 193:15 203:17 222:20 230:8 231:18 244:21 <b>discussed</b> 102:5 158:10 172:20 214:24 242:4 <b>discusses</b> 30:20 <b>discussing</b> 31:8 169:4 172:5 196:10 237:6 <b>discussion</b> 138:4 151:8 238:17 239:1 249:20 <b>dislodge</b> 104:13 107:1 <b>dislodged</b> 107:1 <b>disorder</b> 46:7 79:21 <b>disorders</b> 86:23 <b>dissolve</b> 58:25 <b>distinguishes</b> 111:21 112:16 <b>district</b> 1:1,1,6 3:7 <b>divide</b> 168:17
--	---	--	--	--

Michael P. Woods, M.D.

Page 269

<b>division</b> 1:2	77:14,18 105:8	53:22 55:5	<b>dr</b> 7:11 33:23	198:15,23
<b>doc</b> 11:16	105:9 109:16	56:9,25 57:6	35:9,11,11,12	217:18 227:20
<b>doctor</b> 8:9 9:16	109:19 114:11	57:16 58:4,15	52:7 76:24	227:23 228:11
10:20 39:23	115:10 136:1	58:17,18 60:6	189:24 190:7	228:14 232:5
40:17 41:19	169:4,7 170:22	70:12 71:4,8	190:10,15	
46:2 48:11	181:9 182:12	76:16,19,21,23	191:3 233:12	<b>E</b>
65:5 102:6	183:21,23	77:15 78:17,20	233:12 242:1	
106:14 110:21	184:1 187:12	78:22 79:9,10	<b>drafted</b> 94:3	<b>e</b> 7:2,2 258:1
111:4,20 115:4	188:3 212:1	79:13,16,25	<b>draw</b> 214:22	<b>earlier</b> 7:12
116:20 122:25	<b>doesnt</b> 9:8 19:17	83:19 84:22	<b>drawn</b> 63:21	63:23 85:22
135:20 137:11	24:13 108:12	88:10 89:21	<b>dream</b> 52:15,20	137:12 149:7
138:8 151:19	136:16 172:12	91:5 92:11	<b>drive</b> 4:11 26:11	149:21 161:4
153:13 170:17	187:23 251:12	93:15,22 95:13	26:22 49:9	186:18 197:19
179:6 187:8	251:18 252:3	95:23 96:4,21	61:8,10,12	197:22 199:6
241:8 246:16	253:10	99:6 100:5,14	75:2,6,10,12	201:5 206:9
250:10 251:22	<b>dog</b> 188:2	100:18,19,20	75:23 116:17	218:2 224:1
<b>doctors</b> 27:22	<b>dogma</b> 99:9	105:15 107:9	185:13	227:3 250:17
169:9 184:6	<b>doing</b> 30:13 32:5	109:5,6 113:19	<b>driving</b> 166:23	252:24
210:13	36:17 68:22	114:18,18	<b>dropout</b> 237:20	<b>early</b> 29:20 63:3
<b>document</b> 1:5	74:5 84:25	116:18,23	<b>drops</b> 155:18	95:14 97:1
48:13,15,16	86:24 90:8	117:3 118:16	<b>drove</b> 226:14	118:6 124:14
75:8,21 115:16	102:15 103:13	121:16,16,23	<b>drs</b> 209:17	140:5 222:1
116:20 117:11	109:13 124:13	126:12 127:7,7	233:12	245:15
122:23 151:23	125:11 128:16	127:9 131:13	<b>drug</b> 63:14	<b>ease</b> 41:8
152:3,4 155:4	133:12 140:5	135:5 136:15	94:10	<b>easier</b> 168:10
183:17	140:24 152:11	136:16,18	<b>dry</b> 162:24	243:13,17
<b>documentation</b>	155:14 162:9	137:24 142:2	<b>dublin</b> 84:13	<b>easiest</b> 159:13
249:7	183:23 187:20	143:14 144:14	<b>due</b> 162:23	<b>easily</b> 40:23
<b>documenting</b>	189:16 204:20	145:15 146:2	168:6 193:25	69:22 194:8
17:24	216:23 218:24	147:3,24,25	<b>duly</b> 7:5 256:7	<b>easy</b> 169:14
<b>documents</b> 14:6	220:23 226:25	148:14 151:4	<b>dura</b> 31:1	<b>eau</b> 6:6
14:20 15:6,12	257:8	156:23 158:11	<b>duration</b> 201:20	<b>economics</b>
15:16,20,25	<b>dollars</b> 187:20	159:11 161:13	124:21	124:21
25:25 26:2,6,7	<b>dont</b> 7:23 15:19	161:19 162:14	<b>ed</b> 116:10,12	
26:16 27:5,11	16:24 17:23	163:18 175:6	225:20	
31:15 34:18,22	19:2,16 20:14	176:19 181:18	<b>edge</b> 109:2,3,4	
35:7 44:8	20:18 24:23	183:15,20	168:16 211:10	
48:18,22 49:4	25:22 26:16	184:7 192:5	227:25 228:18	
51:3,6 62:13	27:16 36:13	212:9 226:18	228:18	
67:17 70:18	37:6,23 38:6	241:19 247:13	<b>edges</b> 108:20,25	
71:18,20,24	38:20 39:15,17	247:17 248:1,8	108:25 109:11	
72:9,18 73:1,8	40:24 41:2,19	249:3,10 253:6	109:15 211:8	
73:10,11,14,15	42:9 43:3,15	253:7,13 254:2	<b>editorial</b> 138:9	
73:19,20 74:3	45:21,21 48:23	<b>door</b> 61:3	<b>edmundson</b> 22:4	
74:9,14,16,24	49:17,25 51:20	137:15,15	81:8	
76:4,10,11	51:22 52:9,10	<b>doubt</b> 219:20	<b>educate</b> 242:7	
			<b>educated</b> 128:19	

Michael P. Woods, M.D.

Page 270

<b>educating</b> 128:12 130:3	<b>employees</b> 14:7 50:9 67:21,24	142:23 145:14 165:7 178:21	1:14,15,16,17 1:18,19,20 2:2	134:5 135:1,8 135:21 169:3
<b>education</b> 60:17 86:18 229:17 242:6 244:19	<b>emptying</b> 224:15	179:12 215:15 238:24 240:15 246:19	2:3,4,5,6,7,8,9 2:10,11,12,13 2:14,15,16,17	180:13,17,22 181:25 182:3 184:4,5 226:1 247:3,14 249:8
<b>educational</b> 57:14 243:18	<b>encapsulated</b> 175:22	<b>errata</b> 5:4 257:6 257:9,12 259:6	2:18,19,20,21 2:22,23,24	<b>ethicons</b> 44:6 57:25 129:12
<b>educator</b> 135:13	<b>encased</b> 213:14 255:10	<b>error</b> 138:9	7:14 10:21	131:20,22 135:15 136:2
<b>effect</b> 47:22 235:21,24	<b>endeavor</b> 85:3	<b>especially</b> 45:4 124:13 130:8	12:11 13:3,19 14:6,15 15:8	<b>europe</b> 29:1 110:11 126:21
<b>effective</b> 95:3	<b>ended</b> 58:5	135:9 165:5	15:15,19,25	<b>European</b>
<b>effectiveness</b> 35:20 151:20 152:17	<b>endpoint</b> 164:23 164:25 165:14 165:17	176:25 242:15 248:12	16:5 18:13,20 22:14,22 23:1	217:13
<b>effects</b> 99:25 100:5,10 155:5 231:19	<b>energy</b> 124:22 <b>engin</b> 248:1	<b>esq</b> 4:4,4,10,15 <b>essure</b> 130:10,12	23:13 25:24 27:5,10 31:15	<b>evaluate</b> 143:3 155:5 166:12 166:13
<b>efficacious</b> 195:20	<b>engineer</b> 94:12 209:10	<b>establish</b> 133:9 235:5	33:5,11,14,18 33:24 35:10,13	<b>evaluated</b> 180:13 208:9
<b>efficacy</b> 14:11 14:23 173:21 187:17 193:7 193:24 207:23 208:7 215:14	<b>engineering</b> 90:12,14	<b>established</b> 151:21 152:18 153:24	37:18,19,21,24 37:25 38:4 42:21 44:8,11	<b>evaluating</b> 14:10 150:7 180:9
<b>effort</b> 24:6,18,21 125:10	<b>engineers</b> 96:9 98:21 184:6	<b>estate</b> 33:10,20	46:22 50:9	<b>evaluation</b> 43:8 105:22 200:22
<b>eight</b> 221:4	209:12 241:14	<b>estimate</b> 66:23 136:13,14	56:20,24 57:7 57:11,21,23	<b>evenings</b> 125:4
<b>either</b> 46:10 54:20 97:1 145:13 146:15 158:16 190:21 207:14 211:14 211:18 231:12 256:18	247:21,24 248:1	140:4 145:7 219:13 226:20	60:1,10,18 62:9,11 64:10 64:22 67:21	<b>event</b> 123:2 256:19
<b>element</b> 230:11	<b>ent</b> 95:5	<b>estimates</b> 148:25	68:5,13 74:14	<b>events</b> 130:4
<b>elicit</b> 143:18	<b>entered</b> 115:19	<b>et</b> 1:7,7,8,8,9,10	80:13,15 87:6	<b>everybody</b> 184:22
<b>eliminate</b> 180:12	<b>entire</b> 232:9	1:10,11,11,12	87:12,18,21	<b>evidence</b> 14:10 25:13 72:4
<b>elliott</b> 50:13 233:12 250:3	<b>epithelium</b> 244:4	1:12,13,14,14	88:3,6 89:15	192:17,18,24
<b>elser</b> 80:23	<b>equal</b> 41:23	1:15,16,16,17	97:17 103:3,3	193:12 195:3
<b>email</b> 4:7,7,13 4:17	<b>equaling</b> 224:18	1:18,19,19,20	103:12,16	195:12 198:11
<b>emails</b> 74:4	2:20 2:2,2,3,3	1:20 2:2,2,3,3	73:13 74:6	
<b>employ</b> 242:11	<b>erode</b> 199:8	2:4,4,5,5,6,7,8	109:9 110:3	110:1 157:15
<b>employed</b> 83:20	<b>erosion</b> 12:4	2:9,10,11,12	112:11 114:11	172:1,16,25
<b>employee</b> 83:21	32:16 145:13	2:12,13,13,14	115:4 118:9	173:2,4,20
	146:17 147:21	2:15,15,16,16	121:15,25	177:8,13
	148:18 166:4	2:17,18,19,19	123:1,21,24	189:18,21
	166:17 167:20	2:20,20,21,22	124:11,19,25	
	167:24 179:7	2:22,23,23,24	125:17,21	
	179:19 190:23	2:24 124:22	128:11 129:7,9	
	190:25 197:17	189:13 201:10	129:15,18	
	198:24 208:18	246:11	130:5 131:3,6	
	210:3,19	<b>ethical</b> 132:11	131:9,15,24	
	217:18 239:3,9	<b>ethically</b> 176:25	132:8,9,11,15	
	<b>erosioni</b> 146:16	<b>ethicon</b> 1:3,7,8,9	132:18,22	
	1:10,11,12,13	<b>erosions</b> 11:9	133:4,21 134:2	

Michael P. Woods, M.D.

Page 271

240:5,15	67:11 102:20	77:9,14 78:3,5	<b>extensively</b> 19:4	96:12
245:21 246:3,5	102:21 115:12	86:20,23 90:11	124:19 219:22	<b>feel</b> 21:19 24:19
246:12	115:13 116:3,4	90:13,15,19	<b>extent</b> 128:2,8	46:9 74:17
<b>evidencebased</b>	117:9 119:20	91:6 92:15,18	<b>extrusion</b>	92:8 98:3,12
15:22	119:21 120:11	92:19 93:12,14	239:18 244:2	135:7 142:5,9
<b>evolution</b> 84:19	120:12,21,22	94:14 96:11	<b>extrusions</b> 240:7	142:12 150:1
97:20 99:2	122:8 191:21	97:23 98:1	<b>eye</b> 215:21	153:17 157:10
110:11 222:6	192:7 196:7	106:18 109:25	216:14	158:25 165:24
231:3	197:21 199:19	126:24 142:6	<b>eyes</b> 19:22	169:18 171:2
<b>evolves</b> 98:14	199:22 201:2	148:18 178:11	175:15 178:5	211:18
<b>exact</b> 36:1,10	201:11 217:7	196:11 203:12	<b>F</b>	<b>feeling</b> 110:15
38:12,21 39:12	223:17,20	209:3 223:22		224:15
39:24 40:7,13	225:12 227:14	231:17 233:7	<b>facetoface</b> 51:14	<b>fellowship</b> 82:8
40:18,22 41:1	227:18 236:17	233:11 234:19	<b>fact</b> 60:4 131:23	82:11,14 84:22
41:2 43:3 60:6	<b>exhibits</b> 5:12 6:3	241:1 246:2	219:11	<b>felt</b> 25:20 29:20
76:13 95:13	71:7	250:4 253:24	<b>factors</b> 193:25	41:23 42:4
96:3 127:8,9	<b>exist</b> 8:10 10:14	<b>expertise</b> 86:5	<b>fail</b> 257:15	43:2 69:15
147:4 149:11	13:2 251:18	<b>experts</b> 72:6,19	<b>failure</b> 99:25	70:2,6 84:17
149:16 219:12	<b>existed</b> 62:2	75:9 80:14	100:4,9,13,14	95:3 132:15
<b>exactly</b> 57:8	<b>exit</b> 197:2	98:17 189:25	<b>failures</b> 204:3	135:13 152:17
63:4 70:10	<b>expect</b> 114:25	233:9,10	<b>fair</b> 77:10	158:8 181:11
82:4 85:5	<b>expected</b> 222:5	<b>expires</b> 259:16	235:10 251:16	189:21
99:18 100:14	<b>expenses</b> 55:12	<b>explain</b> 143:5	251:17	<b>female</b> 6:10 8:25
108:22 143:18	55:13 124:2,4	230:4	<b>fairly</b> 219:18	82:19 86:23
<b>examination</b> 3:6	127:19 227:10	<b>explained</b>	<b>familiar</b> 77:4	<b>fibroblasts</b>
5:7,9 7:7	227:13	228:15	236:22	194:9 245:11
246:14	<b>experience</b> 28:5	<b>explanted</b> 91:17	<b>far</b> 75:7 179:1	<b>fibrosis</b> 166:4,18
<b>examinations</b>	34:16 86:5	91:21 92:7	<b>farber</b> 247:8	168:7
197:13	103:11 158:1	158:3	<b>fascia</b> 9:14	<b>figure</b> 32:4
<b>examine</b> 206:22	160:16 201:1	<b>explanting</b>	149:10 186:12	219:18 245:16
<b>examined</b> 7:6	205:18 208:14	175:7	200:12	<b>file</b> 1:3 98:25
<b>example</b> 218:17	210:4 241:10	<b>explicitly</b> 155:4	<b>fascial</b> 138:14	99:5,13
<b>exceeded</b> 105:3	243:6	<b>exposure</b> 198:16	<b>fascinated</b>	<b>financial</b> 133:6
121:9	<b>experienced</b>	199:2 218:18	248:14	<b>financially</b>
<b>excess</b> 194:8	239:12,17,23	224:7,10,17	<b>fashion</b> 51:5	125:13 227:4
<b>excised</b> 149:10	<b>experiences</b>	225:1 243:20	<b>fax</b> 1:24 4:6,12	<b>find</b> 39:7 51:3,6
158:8 239:20	245:19	<b>exposures</b>	4:16	60:19 61:16,20
<b>excision</b> 243:2	<b>experiencing</b>	244:10	<b>fda</b> 28:16 43:7	62:15 64:5,6
<b>excisions</b> 242:24	217:24	<b>expound</b> 149:23	89:13 90:1	66:10 69:1
<b>excited</b> 29:11	<b>expert</b> 5:14 7:13	221:23 230:13	93:19 94:2	101:22 105:5
<b>exclude</b> 161:13	55:20 64:17	<b>expressed</b>	152:7,13,15,16	117:24 147:16
<b>excuse</b> 8:20	70:23 71:2,10	171:21	152:17,20	147:19 180:6
198:25 223:11	71:16,24 72:12	<b>extend</b> 94:22	153:17 155:1,4	187:14 188:2
<b>exercises</b> 35:23	73:1,16 74:15	95:11	207:5 242:3	195:2 207:2
<b>exhibit</b> 48:8,12	75:5 76:4,12	<b>extensive</b> 123:21	<b>feasibility</b> 47:16	216:21 217:11
65:1,2 67:3,9	76:18,24 77:2	123:23	<b>federal</b> 3:6 85:1	229:10 233:23

248:12 252:11	103:13 127:1	<b>foregoing</b>	<b>formulating</b>	<b>funded</b> 47:13
<b>finding</b> 231:1	129:25	256:11,14	198:9,10	<b>further</b> 43:8
<b>findings</b> 47:3	<b>florida</b> 123:15	259:3	233:20	85:3 255:15
<b>fine</b> 45:23 151:2	126:4	<b>forget</b> 241:8	<b>formulation</b>	<hr/>
244:12	<b>focus</b> 188:14	<b>forgot</b> 241:7	237:3	<b>G</b>
<b>finish</b> 21:16	189:9 211:2	<b>form</b> 18:15 20:1	<b>fort</b> 4:12	<b>g</b> 7:2
<b>finland</b> 174:14	228:23	20:23 21:10	<b>forth</b> 256:9	<b>garcia</b> 1:17
<b>finnish</b> 174:4,6	<b>focusing</b> 233:11	23:12 28:2	<b>forwarded</b>	<b>gardener</b> 78:24
<b>fired</b> 250:3	<b>fold</b> 157:18	33:6 39:2 40:1	61:23	<b>gathered</b> 249:2
<b>first</b> 7:5 9:2,13	<b>folded</b> 158:8	41:7,15 44:14	<b>found</b> 61:6,22	<b>gene</b> 50:2,3,5
17:12 23:23	176:17	45:12 49:5	66:1 68:24	<b>general</b> 17:17
24:1 30:4,13	<b>folder</b> 62:4	63:17 73:23	99:8 168:10	18:2,4 29:19
35:22 40:22	<b>folding</b> 158:4	74:11 83:11	177:9 195:3	29:23 139:4
41:1,3 42:16	<b>follow</b> 95:21	89:2 90:16	210:3,17	154:25 155:20
51:17 57:19	111:12 151:22	93:18 94:16	155:21 166:11	
58:2 63:16	164:22 212:17	97:9 98:2,10	221:14 231:18	166:13 167:19
64:7,16 78:1	219:25 220:7	101:7 104:18	255:12	175:20 195:13
82:22 84:7	220:12	106:23 110:6	<b>foundation</b>	205:11 220:18
90:25 99:7	<b>followed</b> 47:11	110:24 113:24	18:16 25:6	234:7 256:5,24
115:3 179:14	110:16 161:7	114:20 122:12	86:8 110:7,25	<b>german</b> 167:15
200:10 201:12	162:1 196:2	123:25 127:6	113:25 122:1	<b>getman</b> 3:10
207:16 223:24	<b>following</b> 11:5	127:23 129:23	122:13 123:25	<b>getting</b> 137:16
223:24 228:4	108:15 162:3	146:4 148:7	129:23 134:23	221:11 226:15
237:11 254:10	164:15,20	156:16 157:20	169:11	251:5,14 252:3
<b>fistula</b> 79:22	221:16	158:14 159:2	<b>four</b> 42:20 44:11	253:8
<b>five</b> 42:20 48:1	<b>follows</b> 7:6	159:10 160:1,8	137:2 141:4	<b>gillum</b> 2:15
110:13 125:10	<b>followup</b> 6:7	160:14 163:25	<b>frames</b> 125:6	<b>gist</b> 71:1
136:5,6 139:16	164:11 187:8	165:2,22 166:5	<b>francisco</b> 123:9	<b>give</b> 9:9,17 12:6
140:1 145:6	197:2 206:1	167:21 168:8	<b>fray</b> 108:19	42:1 52:3
162:19,25	216:4,6 217:16	168:23 169:11	109:15	75:22 78:13,23
163:4,5 226:21	222:22 223:4	170:13 171:9	<b>frayed</b> 109:3	92:13 103:20
237:13 238:2	237:16,18	171:14 173:11	<b>fraying</b> 108:21	136:11,12
238:14 239:8	239:4 250:18	177:5,25 178:9	108:21,23,24	154:6 218:6
<b>fiveyear</b> 6:11	<b>followups</b> 196:1	181:4 183:13	109:1,6,7,9,11	226:20 252:11
47:6 236:20	<b>footnoted</b> 75:8	185:22 186:8	109:17,20	<b>given</b> 78:9 88:25
237:17 239:4	<b>footnotes</b> 71:15	189:14 229:3	232:18	89:5 103:23
239:25 240:3	<b>force</b> 5:15 102:9	252:5 253:12	<b>free</b> 47:1 124:14	162:20 259:4
<b>flash</b> 185:13	102:11,14	259:5	<b>frequently</b>	<b>gives</b> 8:22
<b>flexibility</b>	104:12 105:23	<b>formal</b> 17:3,24	218:23	<b>giving</b> 15:20
228:16	106:6,11 107:5	248:5,7,9	<b>friend</b> 204:21	202:20
<b>flipping</b> 119:25	<b>forces</b> 102:6	<b>formalin</b> 175:9	<b>front</b> 19:22	<b>glad</b> 115:10
<b>floor</b> 29:15	104:2,6,9,15	<b>formation</b> 11:25	<b>frustrating</b>	253:25
35:22,23 62:24	104:15 105:3,4	194:5	130:23	<b>glasses</b> 56:12
79:21 86:2,5	106:20,21	<b>forming</b> 15:16	<b>fully</b> 169:19	<b>go</b> 9:2,9,13,22
86:23 89:14,25	107:11	15:20 16:1	<b>function</b> 231:20	11:5 13:5 18:3
101:20 102:6	<b>ford</b> 192:2	68:6	232:3 239:10	24:4 26:15,18

Michael P. Woods, M.D.

Page 273

28:3 30:6 33:7	142:13 145:9	<b>groups</b> 31:11 93:1 238:5,8,9	236:20 <b>handing</b> 192:10 199:22	57:25 <b>healthcare</b> 23:5 36:21
39:9 46:2	149:14 154:11	<b>guess</b> 70:11 119:14,18	<b>handknitted</b> 206:19	<b>hear</b> 41:16 45:20 108:21
48:19,25,25	161:2,13	134:11 135:3	<b>handled</b> 118:18	158:5 227:5
55:4 65:23	162:13,15,18	136:9,11,15,16	<b>handles</b> 211:16	<b>heard</b> 19:8 77:6
70:13 87:12	179:3 180:7,20	136:17 138:9	<b>hands</b> 101:13 130:21 141:11	99:18,22,23
88:19 89:7,11	185:11,14	144:11 154:6	255:4	157:3,4,8 158:3,23
101:8 104:20	187:9 188:8,17	163:10	<b>handy</b> 151:3	181:17,23
115:8 118:24	190:9 215:23	<b>guesstimate</b> 146:18 147:22	<b>hanson</b> 79:5	<b>hellhammer</b>
122:25 124:15	217:7 243:11	159:7	<b>happen</b> 52:17 179:21 202:19	186:14
126:21 137:13	249:17	<b>guideline</b> 8:24	<b>happened</b> 82:3 179:9 182:14	<b>help</b> 138:17,22
137:24 138:3	<b>gold</b> 149:11,14	<b>guidelines</b> 93:20 94:2 195:8	<b>happening</b> 29:12	<b>heres</b> 243:13,17
144:23 147:21	149:18,20,25	199:23 213:17	<b>happy</b> 141:5 238:15	<b>hernia</b> 5:22
152:19 153:2	150:5,9,12	231:23	<b>hard</b> 147:23,24 147:25 148:25	29:14,17 31:23
153:12 157:15	167:13 190:20	<b>guy</b> 50:13	<b>harlan</b> 23:8	71:21,25 72:2
161:8 162:15	223:15,25	<b>guys</b> 250:1	<b>harm</b> 189:12	166:25 167:5,8
162:18 169:17	249:24	<b>gyn</b> 118:7	<b>harmon</b> 2:9	187:12,20
171:25 173:12	<b>golkow</b> 1:24,25	<b>gynecare</b> 102:8	<b>harvesting</b> 216:18	188:2,3 233:22
179:2 185:23	<b>good</b> 30:15	<b>gynecological</b> 195:18	<b>harp</b> 23:8	234:2,2
187:4,9 200:10	96:17 130:21	<b>gynecology</b> 58:24 59:13	<b>harnias</b> 190:2 230:25	29:11,12
207:16 208:24	131:1 133:16	82:19 139:4,6	<b>hes</b> 15:11 19:1	30:25
215:18 225:8	137:5 146:18	228:3	21:14,15 26:22	31:1,2
228:1,8 230:15	150:23 151:6	<b>H</b>	39:3 49:21	32:1
243:20 244:5	246:22	<b>half</b> 226:12,12 227:12	51:22 185:16	33:1
245:2 249:23	<b>goodwin</b> 1:5	<b>halfday</b> 51:16 51:17,18	221:6,8 250:3	34:1
249:24 252:14	<b>goretex</b> 30:25	<b>hallways</b> 93:8	252:18	35:1
253:5,9	31:19,25 32:8	<b>hammock</b> 104:3	<b>hesitancy</b> 224:16	36:1
<b>goal</b> 140:19	32:12 34:3,4,7	<b>hand</b> 36:7,12 39:14,21 48:11	<b>hesitant</b> 245:20	37:1
<b>goes</b> 98:8 152:24	34:12,15 80:25	115:11 116:2	<b>hey</b> 243:15 252:14	38:1
153:1 154:12	206:18 210:7,8	119:19 120:10	<b>high</b> 32:16 165:12 190:23	39:1
<b>going</b> 7:22 8:21	230:25 245:2	120:20 122:7	208:18	40:1
9:2,13 11:2,4	<b>government</b>	142:1 164:24	<b>higher</b> 68:2 150:20 207:14	41:1
14:12 15:2	79:12 85:1	165:13 190:9	208:11,21	42:1
25:17 29:6	95:25 96:2	242:16 256:20	210:3 229:2	43:1
48:11 51:2,5	<b>governmentsp...</b>	<b>handed</b> 62:4	246:5	44:1
55:1 63:24	192:14	223:20 227:17	<b>higherlevel</b> 70:7 <b>highest</b> 135:15	45:1
64:25 66:12,25	<b>grams</b> 101:21		193:11,12,22	46:1
68:21,24 70:20	102:10 104:7			
71:4 77:24	<b>grand</b> 4:5 89:14			
82:14 84:8	<b>graph</b> 104:1			
86:7 89:11,11	<b>gray</b> 79:3			
101:1 102:19	<b>great</b> 12:3			
110:18 115:8	<b>greater</b> 18:12			
115:11 116:2	<b>group</b> 24:10			
118:25 119:19	29:4,5 162:16			
120:10 122:7	227:20 238:4,4			
122:25 131:18	238:7,7 240:8			

Michael P. Woods, M.D.

Page 274

198:13 235:1	<b>hoping</b> 216:21	37:11,15,16	51:11,11 53:25	192:10 199:22
240:4	<b>hospital</b> 19:17	38:4,7 70:12	54:2 55:1,25	212:8 215:19
<b>highestlevel</b>	22:4,8,11,16	98:13 118:1,2	56:15 57:6	215:24 216:20
84:25 189:17	22:19,23 23:3	118:19 121:13	58:10,11 63:3	222:1,3 231:7
192:24 195:3	23:4,6,6,8 36:3	133:12 136:20	64:9,25 65:8	233:11 235:17
<b>highestquality</b>	36:4,20,21	169:7 202:14	66:9,22 67:7	237:11 243:15
246:12	59:2 81:8,9	<b>ideally</b> 47:25	72:1 76:13	249:17,21
<b>highland</b> 4:15	83:1,22 87:17	<b>ideas</b> 97:13	77:4 82:4	250:7
<b>highlevel</b> 35:5	93:5,9	<b>identification</b>	83:19 86:7	<b>immediate</b>
170:1 173:14	<b>hospitals</b> 18:3	48:9 65:3	88:21 89:7,11	141:3 204:23
217:6 235:18	22:2,13,25	102:22 115:14	89:19 90:10,13	<b>immediately</b>
<b>highquality</b>	23:10,20 36:8	116:5 119:22	92:24 95:19	224:14
175:16 195:17	36:17,23 37:3	120:13,23	96:11,19 97:16	<b>impact</b> 74:17
<b>hilton</b> 162:15	37:6,11,18	122:9 191:22	98:14 99:18	172:21 187:23
163:8	<b>host</b> 194:11	192:8 196:8	100:2,17 101:1	203:9 204:23
<b>histologic</b> 194:3	<b>hotel</b> 88:9	199:20 201:3	101:13 102:19	204:24 212:11
<b>histology</b> 90:20	226:15	223:18 227:15	103:12 108:21	<b>impacts</b> 21:19
90:24 91:1	<b>hour</b> 55:3,6,9	236:18	108:22 109:20	211:18
<b>history</b> 98:25	71:12,13	<b>identify</b> 191:3	110:18 112:8	<b>imperative</b>
99:4,13 143:19	<b>hours</b> 50:22,25	<b>identifying</b>	112:21 114:9	257:11
221:25	53:6,6 54:14	191:14	115:11 116:2,7	<b>implant</b> 106:7,9
<b>hitting</b> 222:3	54:23,24 55:2	<b>ifu</b> 93:17 94:3	119:6,7,15,18	106:22 142:11
<b>hold</b> 20:22 21:14	66:19,22 70:17	242:16	119:19,25	170:9 171:11
45:18,18 51:21	70:21 183:25	<b>ii</b> 130:15	120:10,16	196:18,24
52:6 75:16	<b>house</b> 226:4	<b>iii</b> 30:12 210:2	122:7,18,25	211:19 228:17
109:5 127:4	<b>howard</b> 76:20	<b>ilioinguinal</b>	123:20,20	<b>implantation</b>
132:24 143:5	<b>huge</b> 26:14 74:2	149:9	127:4,4,11	164:15,20
186:4,21	124:22 125:9	<b>ill</b> 9:9 14:24 20:7	131:11 135:4	196:24 204:15
190:24	134:16	36:4 62:6 66:9	135:22 136:1,4	213:8 255:6
<b>home</b> 54:20	<b>human</b> 102:10	165:13 185:18	137:21 140:11	<b>implanted</b> 22:2
<b>honest</b> 40:25	<b>humans</b> 207:4	216:14 221:5	140:17 141:1,4	42:20 91:14
42:2 52:3 54:2	<b>humbert</b> 2:14	228:1 235:10	142:11 145:9	92:16 104:11
57:16 80:1	<b>hundred</b> 125:7	237:24 249:24	147:18,19	135:21 139:20
92:14	<b>hypothetical</b>	<b>im</b> 7:11,22 8:21	150:25 154:6	146:22,24
<b>honestly</b> 37:16	97:10 114:24	9:13,16 10:6	154:11,25	147:7 154:3
42:9 52:8	<b>hysterectomy</b>	11:2,16 14:12	161:2,12	197:14 250:21
70:12 109:6	63:5 79:23	15:6 16:5,18	162:13,15,18	253:11 254:20
136:18 157:10	94:22 97:5	17:2,15 18:17	163:24 166:22	254:23
241:19	<hr/>	20:7 24:2,24	167:14 169:25	<b>implantee</b>
<b>honesty</b> 56:9	<b>I</b>	25:10,17,22	169:25 172:15	196:17
<b>hong</b> 87:9,16,19	<b>ia</b> 256:4	27:21 30:6	175:10 179:3	<b>implanter</b>
87:24 88:23	<b>icon</b> 59:6,16	34:4 35:17,17	180:7,13	196:16
89:6	83:23 84:2,2	35:18 36:7	185:11 186:15	<b>implanting</b>
<b>hook</b> 168:15	85:8 96:13,20	37:19,22 38:17	186:17 187:3,9	25:10 132:22
<b>hooked</b> 104:11	100:24	39:7 41:16	187:19,21	132:24 142:10
<b>hope</b> 117:8	<b>idea</b> 19:23 20:14	45:20 48:11	188:8,17 190:9	142:13 212:8

Michael P. Woods, M.D.

Page 275

255:3	97:10 224:14	168:18 169:19	<b>initial</b> 31:21	44:7 67:17,24
<b>implants</b> 111:19	<b>incon</b> 218:21	<b>incorporation</b>	190:22 222:2	70:18 73:10,11
190:13	<b>inconsistent</b>	245:10	<b>initially</b> 183:22	74:3,14 76:10
<b>implication</b>	200:21 202:10	<b>increase</b> 166:17	230:16	76:11 77:14,18
170:2 177:9	205:17 240:23	236:9	<b>injury</b> 9:20,20	105:8,9 109:16
<b>implications</b>	240:25 241:5	<b>increased</b> 43:7	10:1,1 11:9	114:10 136:1
172:5	<b>incontinence</b>	110:14 115:1	12:15 55:19	169:3,6 170:22
<b>implies</b> 215:19	5:24 6:5,10	231:1 232:5	56:2	182:11 183:23
<b>importance</b>	8:25 28:8	<b>increases</b> 167:20	<b>input</b> 209:13	184:1
217:20 230:5,8	31:11 35:16	<b>increasing</b>	<b>inside</b> 62:5	<b>international</b>
<b>important</b> 67:23	79:19 130:1	114:15 166:3	93:17	47:25 100:23
68:6,15 192:18	140:18 151:15	215:14	<b>instance</b> 196:4	101:2 153:7
214:16 215:1	153:7 167:14	<b>incredibly</b>	<b>instances</b> 46:9	<b>interrupt</b> 19:2
230:11	188:5,24 189:6	179:10	46:14	<b>intersurgeon</b>
<b>importantly</b>	189:7 190:6,14	<b>indepth</b> 76:1	<b>institutions</b>	130:22
196:17	190:17 191:5	77:24 184:8	92:25	<b>intolerability</b>
<b>impression</b>	191:10,15	<b>index</b> 5:1,3 6:1	<b>instructions</b>	202:4
205:12	192:21 193:8	<b>indicate</b> 178:17	108:15 242:7	<b>intraabdomin...</b>
<b>improved</b>	193:17 194:17	<b>indicating</b> 84:5	242:10 257:1	30:11
140:21 232:3	194:25 195:8,9	<b>indication</b>	<b>integral</b> 99:8	<b>intraoperative</b>
<b>improvement</b>	195:21,24	101:15	<b>integrate</b> 209:1	216:1
40:18 41:5	196:13,23	<b>individual</b> 119:6	<b>integration</b>	<b>intraoperatively</b>
207:19	197:25 198:6	<b>individualized</b>	184:24	156:15 157:2,5
<b>incidence</b>	199:9 200:7,24	46:12	<b>intended</b> 188:19	<b>introduced</b> 25:2
198:23 199:1	201:15,25	<b>individuals</b>	188:22 189:4	<b>invasive</b> 228:3
199:16 235:8	202:5,25	98:22	190:5 191:4,15	<b>invented</b> 133:10
<b>incident</b> 82:3	203:15,20	<b>infection</b> 9:15	192:20 202:8	<b>inventors</b> 133:8
<b>incise</b> 244:6	204:17 205:6	9:19,25 11:25	203:15 206:11	<b>investigated</b>
<b>incision</b> 197:3	206:3,12,16,25	194:12 198:16	209:5 213:2,7	188:20 189:13
<b>incisions</b> 216:19	207:16 209:6	199:14,17	213:13 232:7	<b>investigator</b>
<b>include</b> 12:14	209:18 210:1	231:1 239:9	233:19 241:3	62:23 63:3
13:14 50:25	210:14 211:17	<b>infections</b> 9:19	<b>intercourse</b>	84:8
53:8,11 55:12	212:6 213:3,14	9:21 10:3	161:14 163:2	<b>invited</b> 87:16
152:13 161:1	213:16 216:25	193:23 199:12	<b>interest</b> 30:24	89:17
164:7 165:6	217:4 219:23	208:19 230:22	133:19 139:12	<b>involve</b> 79:18
<b>included</b> 152:8	220:10 221:18	<b>infiltrate</b> 168:14	245:14	195:5
152:10 164:11	222:14 224:23	244:3,7	<b>interested</b> 29:9	<b>involved</b> 98:17
165:7 237:12	229:1,10,19	<b>inflammatory</b>	30:9 42:17	100:10 108:2
238:1	231:25 232:2,8	194:4	256:18	180:19 228:13
<b>includes</b> 11:8	233:20 235:1	<b>inform</b> 133:3	<b>intermittency</b>	241:17 249:5
50:23	235:14 239:20	240:10 250:22	224:13	<b>involvement</b>
<b>including</b> 12:2	241:3	<b>informal</b> 248:10	<b>internal</b> 14:6,20	64:21 87:18
12:23 17:17	<b>incorporate</b>	<b>information</b>	15:6,16,20,25	241:13
44:8 191:18	245:6	14:22 93:16	25:24 26:6,6	<b>involving</b> 56:3
193:25 216:4	<b>incorporated</b>	160:23	26:16 27:5,10	<b>iowa</b> 22:6 23:4,5
<b>incomplete</b>	112:2 168:13	<b>ingrowth</b> 194:11	31:14 35:6	82:24,25 83:5

Michael P. Woods, M.D.

Page 276

83:10 135:24	<b>jones</b> 2:13 4:4	176:11 238:25	126:5,25	44:17 45:14,21
<b>iquinto</b> 1:9	<b>jordi</b> 76:20	<b>kinds</b> 74:7	129:18,19	46:1 48:2,10
<b>irbapproved</b>	<b>joseph</b> 1:5	<b>kit</b> 44:23	131:11 134:16	49:23 52:14,20
32:6	<b>journal</b> 228:2	<b>kits</b> 142:8	135:16,18,20	52:22 56:15,19
<b>ireland</b> 162:16	<b>judge</b> 1:6 188:7	<b>klinge</b> 167:7	136:18 148:16	61:21 62:1,6,7
<b>irvine</b> 123:13	188:9	189:24 190:7	158:10,13	63:18 65:4,10
<b>isnt</b> 165:16	<b>judges</b> 188:11	190:15 191:3	163:18 164:6	67:6 69:7
<b>iso</b> 100:21,22	189:8	<b>klinges</b> 190:10	167:4 170:6	73:24 74:12
101:5	<b>july</b> 64:18	<b>knew</b> 14:7 15:8	171:16 176:19	75:4,16,20
<b>issue</b> 78:19	<hr/>	<b>knits</b> 194:1	180:19 181:18	83:13 86:11,19
81:21	<b>K</b>	<b>knitted</b> 138:15	181:25 182:22	89:3 90:18
<b>issued</b> 81:22	<b>k</b> 182:1,17,20	138:16,22	182:25 183:3	93:21 94:19
<b>issues</b> 67:25	<b>kaiser</b> 173:24	<b>know</b> 7:18 12:10	184:7,9,12,14	97:11 98:7,16
68:16 79:18	<b>kammerer</b> 50:2	13:1,19 14:14	184:18,25	101:11,24
<b>iua</b> 6:7	50:3,6	15:3 18:20,25	185:3,5 186:14	102:3,24
<b>ive</b> 14:21 36:2	<b>kansas</b> 4:6 89:13	19:16,20 22:19	186:16 198:16	103:15 104:23
42:4 51:4,19	126:17	30:7 33:4,10	202:17 205:12	105:17,21
54:7 57:7	<b>keep</b> 16:14,15	33:13,17,20,23	210:6,13	106:3 107:3
61:14 76:7,8	20:18 53:23,25	35:9,12 36:8	215:25 216:8	110:18,20
91:14 92:16,20	54:12 58:18	37:2,7,17,23	225:25,25	111:3,6 114:2
92:22 97:21	60:16 62:13	38:9,21,25	227:11 241:11	114:21 115:15
99:18 146:21	89:20 114:6,7	39:1,4,12,17	243:23 248:14	116:7,9,11,14
146:22 159:12	118:8,12,25	39:19,23 40:12	248:16 249:3	116:16,19
168:24 205:1	121:17 138:22	40:24 41:2,18	251:13 252:22	117:5,10
207:8 214:10	146:2,23	42:7,9,10,13	253:7,7	119:23 120:14
217:23 222:4	147:23,24,25	42:14,24 43:3	<b>knowledge</b>	121:1,3 122:4
227:17 236:20	148:9 218:23	43:5 44:18	13:19,24 14:15	122:10,16,24
243:13,17	246:18 247:17	50:3 52:9,10	29:13 52:9,11	124:1 126:14
<hr/>	<b>keeping</b> 16:16	58:4,11 61:10	95:24 98:4,5	127:12,24
<b>J</b>	246:22	61:18 62:1	101:4 220:19	128:9 130:2
<b>j</b> 134:16,16	<b>kelly</b> 2:20	66:15 68:9	<b>kong</b> 87:9,16,19	134:24 135:6
<b>january</b> 58:2	<b>kenton</b> 80:24	71:12 75:7,12	87:24 88:23	136:14,21
225:17	85:21	76:7,15,16	89:6	137:5,9 138:5
<b>javins</b> 2:4	<b>kept</b> 16:20 17:6	79:12,15 80:14	<b>kuntz</b> 4:4 5:7,9	138:7 146:6,11
<b>jeff</b> 7:11	21:7,7 23:19	80:20,22,24	7:8,11,25 8:3,7	148:5,8 151:4
<b>jeffrey</b> 4:4	60:9,19 80:3	82:13 93:15,22	8:8 13:8 14:4	151:11 153:19
<b>jennie</b> 22:4 81:7	119:2 146:25	95:13,25 96:2	14:24 15:1,14	154:1 156:19
<b> jewell</b> 76:14	151:5 219:2,5	96:3,4 97:7,16	18:18,24 19:7	157:23 158:19
<b>jkuntz</b> 4:7	249:7	99:12,17,21	20:3,6,13 21:2	159:6,14 160:4
<b>jobs</b> 59:4,5	<b>key</b> 129:19	100:5,8,12,14	21:12,20 23:15	160:11,17
<b>johnson</b> 57:25	<b>khan</b> 249:4	100:16,18	25:16 26:17,21	163:22 164:5
57:25 58:7,7	<b>kicked</b> 226:18	106:1,5 109:6	26:24 27:3	165:8 166:1,7
58:21,21 129:9	<b>kim</b> 80:23	110:3 114:18	28:6 33:9 39:4	168:4,20 169:2
129:10 137:14	<b>kind</b> 51:7 64:1	116:18 117:25	39:7,11,22	169:12,22
137:14	69:18,23 72:2	118:16 121:9	40:4,9,11	170:16 171:12
<b>jointly</b> 69:18	93:3 161:8	121:21 124:10	41:12,17 42:6	171:18 173:16

Michael P. Woods, M.D.

Page 277

174:10,16	<b>lambert</b> 2:6	226:10	157:15 172:13	71:11 72:11
177:10 178:1	<b>lamborghini</b>	<b>lately</b> 142:6	172:24,24,25	73:3,20 77:10
178:13 181:8	166:23	145:5	177:8,17	77:19 105:10
183:16 185:17	<b>laparo</b> 207:9	<b>laterally</b> 244:6	193:12 195:12	105:12 126:5
185:24 186:13	<b>laparoscopic</b>	<b>launch</b> 15:9	198:11,13	134:14 147:1,3
187:3,15 188:8	140:2,6	<b>launched</b> 13:20	216:11 233:21	161:21 182:12
189:1,14	<b>laparoscopic...</b>	13:25 14:8,17	233:21 234:15	183:11 189:20
190:18 191:16	207:8	<b>laurikainen</b>	234:20 235:2	253:25
193:10 194:18	<b>laparoscopy</b>	236:21 249:4	240:5 246:5	<b>listed</b> 1:6 9:6,7
196:14,25	139:12	<b>lawsuit</b> 67:25	<b>levels</b> 14:10 70:6	10:25 12:22,25
198:18,21	<b>large</b> 141:25	<b>lawsuits</b> 80:10	192:17,18	14:16 15:8
202:6,12 203:2	167:20 183:8	<b>lawyers</b> 260:1	<b>lewis</b> 76:25 77:3	50:2 56:5
204:18 205:20	183:14,22	<b>lead</b> 190:23	77:4,6	71:10 77:9,20
206:4,9 207:1	195:16 234:2	<b>leading</b> 187:15	<b>liability</b> 1:4	162:10
207:24 209:7	<b>largest</b> 84:10	189:15	92:21	<b>listen</b> 52:6,6
209:22 211:7	<b>las</b> 123:11	<b>league</b> 243:23	<b>license</b> 81:2	<b>lists</b> 72:20
212:1 213:4,21	<b>laser</b> 19:11,13	<b>leak</b> 155:18	82:25	246:17
214:9 215:12	19:18,23 20:15	<b>leakage</b> 158:18	<b>licensing</b> 81:20	<b>literally</b> 61:4
218:13 219:1	20:20 21:4,9	<b>learn</b> 24:1 59:7	<b>life</b> 84:20 99:2	195:17
219:16 220:4	21:24 22:8,15	<b>learned</b> 24:16	140:20 141:2,7	<b>literature</b> 28:20
221:3,7 224:24	23:16,21,23	245:12	204:23 245:3	28:22 29:17
229:4,14	24:5,15 25:2	<b>lecture</b> 89:4,12	<b>lifelong</b> 179:7	30:19,20 31:5
232:12,16,20	25:20 26:1	89:24 126:20	<b>lifting</b> 107:12,15	31:7,23 51:4
232:25 234:18	27:6,12,15,17	137:14 226:12	<b>ligasure</b> 94:22	68:19 69:11,20
235:16,22	27:24 38:13	<b>lectureand</b>	95:4,11 242:4	69:22,24 76:7
240:13 241:9	42:8 110:5,10	102:7	<b>light</b> 176:9	110:10 114:13
241:18,20	110:23 111:9	<b>lectured</b> 87:5	<b>lighter</b> 180:13	140:22 141:13
242:13,19,24	111:16,22	128:4 137:16	<b>lightweight</b>	141:14 158:2,7
245:25 246:15	112:6,17	<b>lectures</b> 88:25	185:20	161:6,22
249:21 250:5,9	145:15 149:18	124:7 125:11	<b>limit</b> 102:10,18	163:17 164:3
251:21 252:8	149:22 159:16	127:9	106:8	165:11 171:23
252:21 253:2	159:23 160:6	<b>lecturing</b> 124:9	<b>limitations</b>	171:24 179:19
253:14,25	165:20 210:21	193:1	237:25	182:10 187:23
254:4,25	211:15 213:12	<b>lee</b> 222:4 248:25	<b>linda</b> 85:20,22	188:3 189:10
<b>kutner</b> 79:1	213:20 214:7	<b>left</b> 104:16 226:4	86:3,9	190:1 194:22
<b>kuuva</b> 174:17	227:24 228:17	<b>legal</b> 83:10,12	<b>line</b> 74:4 258:3	194:23 195:4
<hr/>		103:6,9	260:2	200:25 203:14
<b>L</b>		<b>legalese</b> 71:5	<b>lines</b> 202:21	205:13 206:21
<b>lab</b> 91:11 183:6	251:14,19	<b>length</b> 95:2	242:21	207:11,19
<b>labs</b> 124:8	252:3,12,15,23	<b>leukocytes</b> 194:9	<b>list</b> 10:12 12:23	208:5,9,13,15
127:14 242:15	253:6,8,18	<b>level</b> 32:6 34:25	12:25 16:23	208:20 209:15
<b>lack</b> 230:5 233:5	254:17,21	68:2 70:4 72:3	17:3,24 50:1	213:24 214:2,7
244:14	255:6	74:5 84:18	67:3,5,7,8,12	214:11,13
<b>lacks</b> 25:5 86:7	<b>laserly</b> 211:5	98:5 101:14	67:15 68:19,20	220:25 221:14
122:12 123:25	<b>late</b> 63:3 95:17	110:1,2 150:20	68:22 69:2,9	221:20 229:9
<b>lake</b> 125:19	97:1 178:20		69:17 70:19	231:18 233:18

Michael P. Woods, M.D.

Page 278

233:22 235:13	153:18 201:6	165:5 167:10	148:25 154:25	137:10,23
245:22,23	215:6 254:6	171:4 172:13	166:22 167:16	<b>lundell</b> 2:21
246:9	<b>longestterm</b>	173:19,23	169:25 170:1	
<b>litigation</b> 1:4	27:19 211:20	175:7 184:16	175:11 187:22	<b>M</b>
<b>little</b> 41:24	<b>longitudinal</b>	187:21 189:17	204:5,6 207:9	<b>m</b> 1:23 3:5,12
54:18 88:19	140:12	192:15,16	216:20 222:1,3	4:4 7:4 43:20
120:1 138:25	<b>longterm</b> 6:7	196:2 214:14	230:20 231:3,7	46:20 48:6,6
158:17 171:2	27:12,14,17	215:20 216:5,6	236:8 255:4	102:1,1 129:1
179:5 204:11	47:20,24	216:8,14	<b>looks</b> 120:1	137:7,7 174:11
221:10,23	114:14 150:2	220:22 221:20	153:18 179:4	174:11 225:9,9
230:13 231:6	153:3,5,6	221:24 222:24	215:22 246:7	255:16 256:7
248:16	160:20 164:8	224:3,9,10	<b>loose</b> 156:4	259:8
<b>live</b> 131:23	164:13,18,24	227:17 235:1	<b>looseleaf</b> 49:11	<b>machine</b> 104:12
<b>lives</b> 204:24	165:14 173:2	237:11 245:15	<b>loosely</b> 156:2,5	<b>macrophages</b>
206:7	190:25 202:3	246:8,10 249:1	159:24	194:9 245:6,9
<b>lip</b> 3:10 4:5,10	203:6,14 204:6	253:24	<b>lord</b> 154:15	<b>macroporous</b>
4:14	204:8 206:1	<b>looked</b> 28:24	<b>loss</b> 125:5	18:12 29:21
<b>local</b> 18:2,5,8	211:21,24	29:21 30:4	<b>lost</b> 89:22 124:9	30:23 31:4
168:14 243:9	215:4 223:8	59:25 61:3	<b>lot</b> 37:22 60:19	42:15 167:12
243:25 244:4,7	224:6,22 236:2	67:15 69:25	60:20 61:17	167:23 168:2
<b>locate</b> 10:7	236:8,12	72:23 76:2	62:19 68:12	184:17,23
<b>located</b> 84:3	238:12 239:25	77:20 91:18,20	70:12,15 71:14	190:24 191:7
143:20,21	240:3	93:25 102:9,11	76:7 86:9	191:11 193:20
207:9	<b>look</b> 8:21,23	109:19 110:1	91:14 125:11	193:20 194:7
<b>log</b> 219:3,6	10:15,17 11:2	113:10 128:12	127:8 129:15	194:11 208:6
247:2,13,17	14:9 25:9,12	147:17 148:17	151:18	208:25 210:12
<b>logs</b> 246:19,20	26:5,19,24	152:13 160:21	<b>lots</b> 143:15	220:9 245:5
246:22	30:7,23 39:8	160:22 161:6	180:18	<b>mail</b> 118:11
<b>london</b> 126:23	43:8 48:21	163:17,19,20	<b>low</b> 25:14 110:2	<b>maintain</b> 203:25
<b>long</b> 47:23 66:17	53:21 54:6	187:19 190:1	141:15 179:22	<b>major</b> 216:13
71:9 76:3,11	56:11 62:6,19	210:10 216:12	194:12 205:15	<b>majority</b> 18:6
78:20 83:23	65:23 66:9,12	216:13 230:16	211:23 234:20	215:5 226:19
110:17 112:15	68:1,2 71:19	236:21	238:9,20	<b>making</b> 141:6
140:23 149:19	73:13 74:8,13	<b>looking</b> 15:22	<b>lowe</b> 1:18	<b>malpractice</b>
161:18 162:11	76:6 92:2,5	19:5 21:5	<b>lower</b> 200:17	56:1 78:6,10
167:25 174:6	96:25 99:11	25:10 29:25	204:11 207:22	79:18
203:24 215:23	101:23 109:2	30:14 31:4	208:7	<b>man</b> 249:24
216:10,24	110:9 113:5	49:21 51:2	<b>lowerlevel</b>	<b>management</b>
221:10 225:1	118:23 122:22	68:21 72:3,4	189:21	8:25
<b>longer</b> 42:21	133:16 137:22	74:5 77:23	<b>lowest</b> 172:17	<b>manager</b> 118:10
43:23 47:12	137:23 140:22	85:5 92:9 93:2	<b>lowlevel</b> 178:12	118:18 121:12
83:1,15 133:6	140:23 141:18	93:9 95:2	246:3	247:6,7,9
142:7 147:18	147:15 150:6	97:19 98:24	<b>loyal</b> 134:20	<b>maneuver</b>
179:2,21 196:1	154:8 161:2	99:10 102:5	<b>loyolastritch</b>	155:22 158:16
215:8 250:18	162:4,14	105:2 109:22	91:3	<b>manning</b> 23:4,5
<b>longerterm</b>	164:10,14,19	110:11 120:16	<b>lunch</b> 66:7	36:21

Michael P. Woods, M.D.

Page 279

<b>manufacture</b>	168:16,19	40:7,13 98:21	245:22	26:1,1 27:7,13
43:3	185:5	110:5,23	<b>medicine</b> 59:9	27:15,17,25
<b>manufactured</b>	<b>materials</b> 72:6	111:10,16,22	82:19 214:19	29:21,21 30:10
94:23	75:5 111:15	112:6,17	<b>medscan</b> 99:17	30:12,24,25
<b>manufacturers</b>	194:2,6 196:12	149:17,20	134:5	34:2,7,12,15
63:12,14 95:20	209:19,25	159:16 165:20	<b>meeting</b> 53:9,16	34:19,21,23
<b>manufacturing</b>	<b>matney</b> 2:12	195:6 210:21	53:19 89:13	38:13,16,22
44:1,15,19	<b>matrix</b> 181:22	211:20,22	90:1 131:18	39:13,24 40:13
96:17 98:6	181:23,24	213:11,19	152:20 158:11	42:15 71:21,25
<b>map</b> 143:21	182:7,23 183:3	215:10 229:2	241:13	72:2 80:25
<b>marc</b> 50:16	<b>matter</b> 19:18	229:11 248:21	<b>meetings</b> 29:7	85:7,15 86:21
<b>margoliss</b> 76:24	24:13 159:4	248:23 249:5	51:13,16 53:12	86:25 87:3,6
<b>mark</b> 48:19	237:3 254:18	253:17 254:6	129:13,16	89:1,5,14,25
64:25 66:2	<b>matters</b> 254:16	254:17,21,22	131:7,12,16,21	90:9 91:17,21
102:19 190:10	<b>maximum</b>	255:7	131:23 171:25	92:2,7 101:12
192:5 197:20	115:24 117:13	<b>mechanically</b>	248:3,5,9,10	104:15 106:7,8
<b>marked</b> 5:12 6:3	117:18 118:1,4	19:18 38:19	<b>memorial</b> 23:3,8	106:11,21
48:8,12 65:2	120:3,17 121:6	42:8 109:2	36:20	107:2 109:12
65:11 102:21	122:20 174:22	149:23 150:8	<b>memory</b> 17:2	109:13,17
115:11,13	<b>mcintyre</b> 1:14	160:7 166:14	<b>mental</b> 147:1	110:5,5,10,23
116:2,4 119:20	<b>md</b> 5:14	187:18 211:5	148:24 219:2,6	110:23 111:9
119:21 120:10	<b>mdl</b> 1:4	211:15 215:7,8	246:17,19,20	111:10,16,17
120:12,20,22	<b>meals</b> 88:14	228:21 229:13	246:22 247:2	111:22,23
122:8 191:21	<b>mean</b> 24:8,17,18	236:16	247:13,17	112:6,6,17,17
192:7 196:7	93:4,15 105:19	<b>mechanism</b>	<b>mention</b> 241:18	112:22 113:4
199:19 201:2	108:23 140:18	108:5 241:24	<b>mentioned</b>	113:11,23
201:11 223:17	147:13 176:20	241:25	85:22 174:1	114:5,8,12,22
227:14 236:17	215:18 221:7	<b>mediate</b> 174:14	189:24 192:17	139:20 141:21
<b>market</b> 42:22,25	227:7 248:24	<b>medicaid</b> 83:6	193:5 197:19	142:1,3,23
43:25 44:12	<b>meaning</b> 101:18	<b>medical</b> 23:2	199:6 201:5	144:13 145:13
95:14 130:16	<b>means</b> 108:22	36:22 55:25	211:25 238:19	145:14 149:5
130:20 132:19	108:24 109:9	78:2,5,10	241:19	149:17,18
142:7	<b>measure</b> 158:21	79:17 81:2	<b>mersilene</b> 30:25	151:14 155:6
<b>marketing</b> 24:6	<b>measured</b>	85:23 90:20,25	32:15,18,21	155:15,25
24:17,24	104:12	93:13,16 94:3	34:2 206:18	156:12 157:12
<b>marking</b> 65:8	<b>measurements</b>	94:7,15,17,20	210:15,17	157:18 159:16
<b>marlex</b> 210:8,11	102:16	95:1,6,21 98:8	245:20	159:17,23
225:5 245:19	<b>mechanic</b> 211:1	98:9,23 139:3	<b>mesh</b> 8:11,17	160:6 165:6,20
<b>martinez</b> 1:13	<b>mechanical</b> 7:19	173:20 182:10	10:13,21 12:3	166:3,11,12,16
<b>maryland</b>	8:10 20:19	186:25 187:1	18:9,12,13,14	166:17,20,25
125:25	21:4,9,25 22:9	187:17,23	18:20,21 19:4	167:1,2,5,8,11
<b>massive</b> 69:21	23:17,21 24:12	189:10 192:24	19:9,12 20:19	167:13,24
<b>master</b> 1:3	25:21 26:1	194:22 195:4	21:4,25,25	168:2,12
<b>mater</b> 31:1	27:6,25 38:15	208:5 209:15	22:2,8,15	169:23,24
<b>material</b> 26:14	38:21,23 39:13	214:6 220:19	23:23 24:5	170:5,7,20
155:15 166:21	39:15,24 40:3	220:25 221:13	25:2,20,21	171:7 172:6

Michael P. Woods, M.D.

Page 280

175:3,7,18,20	<b>meshes</b> 10:18	155:9 200:3,5	148:6	<b>move</b> 14:24 57:2
175:25 176:2	19:6 25:3	200:16 223:14	<b>misstates</b> 15:10	110:18 186:12
176:12,13,14	112:1 180:10	223:25 232:2	15:11 20:23	<b>moved</b> 56:25
180:4,14,15	185:20 186:4	<b>migrate</b> 34:19	45:13,19	59:1 60:14
184:9,14,15,17	194:7,11	34:24 35:7	114:20 146:9	<b>mucosa</b> 228:19
184:18,23,25	206:10,15,19	<b>migrated</b> 30:11	148:2 164:1	<b>muehl</b> 76:22
185:3 186:1	208:6,7,10,11	<b>migrates</b> 35:2	251:20 252:18	<b>mullens</b> 2:2
190:23 191:3,4	208:16,22	<b>migrating</b> 34:21	252:25	<b>mullins</b> 1:7 7:14
191:7,9,9,12	210:2,6,10	<b>migration</b> 34:1	<b>misstating</b> 15:13	<b>multicenter</b>
191:14 193:16	211:2 225:2,4	34:7,12,15	<b>mixed</b> 188:23	28:25 134:8
193:17,22	229:10 231:10	<b>miller</b> 2:11	189:6	<b>multifilament</b>
194:5,7,16	231:14 244:16	<b>millimeters</b>	<b>model</b> 166:23	193:20 208:7
195:9 197:7	255:13	244:6	<b>modes</b> 99:25	208:10
202:11 203:7	<b>met</b> 7:11 51:8,19	<b>million</b> 154:4,5	100:4,9,13,15	<b>multiincision</b>
206:22,24	<b>metaanalyses</b>	<b>mills</b> 3:10	<b>modification</b>	151:20 152:18
207:13,17,21	207:21	<b>mind</b> 47:24	35:24	<b>multiple</b> 18:3
208:12,23,25	<b>metaanalysis</b>	114:8 127:10	<b>modify</b> 145:23	54:18 103:24
209:2 210:8,15	35:1 70:13	146:25 179:4	<b>moines</b> 187:2	180:20 203:18
210:21,23	141:19 150:19	203:23 219:20	<b>molehill</b> 252:20	<b>myrtue</b> 23:8,9
211:1,2,4,12	162:8 173:6,22	<b>mine</b> 25:11 81:8	<b>moment</b> 66:3	36:19
211:14,15,22	189:19	178:6	115:23 174:9	<hr/>
212:2,8,13,14	<b>michael</b> 1:23 3:5	<b>mini</b> 43:14	<b>moments</b> 66:5	<b>N</b>
212:16,20,21	7:4,10 256:6	<b>miniarc</b> 28:10	<b>monarc</b> 35:20	<b>n</b> 7:2
212:23 213:1,6	259:8	28:13 42:7,11	<b>monday</b> 7:1	<b>name</b> 7:9 76:16
213:6,11,12,12	<b>microns</b> 18:12	42:13,16	<b>money</b> 124:9	76:21,23 77:6
213:20 215:7	194:8 209:1	149:25 150:1	134:1 247:14	78:15,18 79:25
215:11 224:7	<b>microporous</b>	<b>miniarcs</b> 35:19	249:8	89:19 99:2,24
224:10,17	193:20 231:13	<b>minimal</b> 155:23	<b>moneys</b> 225:25	100:17 248:1
225:5 227:24	<b>microscope</b>	<b>minimally</b> 228:2	<b>monitoring</b>	<b>named</b> 7:13
229:3,3,12,13	91:21 92:3	<b>minislings</b> 6:9	28:20	11:13 13:1
231:2,8,8,12	<b>microsurgery</b>	<b>minneapolis</b>	<b>monofilament</b>	78:10 80:15
232:4,10,14	245:15	137:4	167:13 191:7	<b>names</b> 30:6
234:1,3,6	<b>micturition</b>	<b>minority</b> 142:25	191:12 194:13	77:25 96:4
239:9 240:15	224:14	<b>minus</b> 16:13	231:14	186:15,17
242:20,24	<b>mid</b> 200:14	17:22	<b>month</b> 219:12	<b>narrow</b> 166:21
243:19 244:8	<b>midline</b> 239:19	<b>minute</b> 12:23	<b>monthly</b> 218:25	<b>nate</b> 4:4
244:21,22	239:22	167:10	<b>months</b> 34:10	<b>national</b> 124:19
245:1,2,5,19	<b>midur</b> 200:22	<b>minutes</b> 20:8	83:25 160:20	171:25 173:23
245:20 248:21	<b>midurethra</b>	<b>misquote</b> 162:14	160:25 161:25	191:17
248:21 249:5	200:14	<b>misquoting</b>	162:6 163:15	<b>nationwide</b>
251:5,19 252:3	<b>midurethral</b>	150:25	163:20 174:15	125:10
252:12,15,18	8:15 10:17	<b>missed</b> 127:5	174:20 179:14	<b>native</b> 10:10,25
252:23 253:6,9	11:11,14 28:19	<b>mississippi</b> 4:16	<b>morning</b> 54:25	12:24 46:10
253:18 254:6	32:13,24	<b>missouri</b> 4:6	137:12	139:10 186:6
254:17,20	144:20 151:14	89:12	<b>mountain</b>	<b>nature</b> 224:8
255:2,7	154:19,25	<b>misstatement</b>	252:20	<b>nearly</b> 11:15

Michael P. Woods, M.D.

Page 281

<b>nebraska</b> 3:10 3:11 7:1 23:2 55:24 81:13,13 81:20 82:24 83:1,2,3,4,6,10 83:14 135:16 135:20 256:2,6	<b>newer</b> 254:7 <b>newest</b> 193:15 <b>nice</b> 8:22 191:19 237:21 <b>nick</b> 76:14 <b>nils</b> 4:10 <b>nilsson</b> 27:11 33:23 152:22 222:25 <b>nilssons</b> 204:7 <b>nine</b> 161:7 <b>njones</b> 4:7 <b>nonethicon</b> 63:7 <b>nonevidenced...</b> 14:22 <b>nonlitigation</b> 57:11 <b>nontvt</b> 233:23 <b>nontype</b> 208:6 208:10,17 220:9 231:13 231:15 244:15	237:15 246:10 <b>numbers</b> 122:3 147:4,23,24,25 148:9,18,24 149:1 <b>numerous</b> 31:1 62:4 164:21 209:9 222:10	196:25 198:18 198:21 202:6 202:12 203:2 204:18 205:20 206:4 207:1,24 209:7,22 211:7 213:4,21 214:9 215:12 218:13 219:1,16 220:4 221:3 224:24 229:4,14 232:12,16,20 232:25 234:18 <b>O</b> <b>o</b> 7:2 <b>oath</b> 136:12 253:7 <b>object</b> 7:23 86:7 148:7 249:17 <b>objecting</b> 45:20 <b>objection</b> 13:4 14:2 15:10 18:15,22 20:1 20:22 25:5 33:6 39:2,18 44:14 45:12,19 <b>norm</b> 222:8 <b>notarial</b> 256:21 <b>notary</b> 3:9 256:5 256:24 259:18 <b>note</b> 20:10 72:14 <b>notebook</b> 49:8 <b>noted</b> 170:23 217:18 259:6 <b>notes</b> 260:1 <b>notice</b> 5:13 56:13 <b>noticed</b> 70:22 <b>november</b> 83:25 225:13 <b>novo</b> 217:18 <b>nuance</b> 130:24 130:25 <b>nuances</b> 142:14 <b>number</b> 16:14 106:1 146:2 147:16 154:17 164:10 183:15 207:7 218:5 219:12,14	196:25 198:18 198:21 202:6 202:12 203:2 204:18 205:20 206:4 207:1,24 209:7,22 211:7 213:4,21 214:9 215:12 218:13 219:1,16 220:4 221:3 224:24 229:4,14 232:12,16,20 232:25 234:18 235:16,22 240:13 242:13 245:25 251:20 252:5,17 253:12 <b>objective</b> 201:21 207:18 223:10 238:3 <b>observational</b> 84:17 <b>obstetrical</b> 59:15 93:3 <b>obstetrics</b> 58:23 59:13 82:18 139:7 <b>obstruction</b> 115:2 <b>obstructive</b> 92:1 <b>obtained</b> 242:3 <b>obturator</b> 128:22 <b>obviously</b> 49:2 <b>occasional</b> 178:24 179:1 <b>occur</b> 108:15 178:21,24 179:13,13 216:19 <b>occurred</b> 132:13 228:11 <b>occurs</b> 176:23 <b>october</b> 1:22 3:2 3:12 7:1
---	---	--	--	---

Michael P. Woods, M.D.

Page 282

36:8 37:2,8,15	83:6,17,21	153:12 154:5	<b>omaha</b> 3:11 7:1	68:6 75:22
37:17 38:4,7	84:2,15 85:2	154:18 156:5	84:14	77:15 178:15
38:20 40:21	86:1,12 87:2,5	157:6,12,17	<b>once</b> 44:12	178:18 198:9
41:4,13,21	87:8,15 88:3	158:2,20,23	104:15 131:23	233:20 237:3
42:10,24 43:10	88:11,17,19	159:19 160:12	155:16 218:24	<b>opportunity</b>
43:17,22 44:2	90:2,24 91:13	160:18,24	231:16	85:4
44:4,7,18,22	91:20,24 92:2	162:11 163:8	<b>ones</b> 8:23 26:8	<b>opposed</b> 104:15
45:1,8,10 46:2	92:25 93:4,7	163:18 165:9	48:23 57:4	111:22 148:25
46:16,25 47:14	93:15,22,25	165:13,18	61:20,22 72:10	<b>option</b> 98:24
47:20,23 48:5	94:9,23 95:6	166:8,15,25	72:14 73:5,21	214:7 218:19
48:15,18,25	95:16 96:6,22	167:18 170:11	96:3 97:20	<b>oral</b> 8:5
49:4,8,22,24	97:2,15 98:17	172:14,18	102:8 118:13	<b>order</b> 22:8,12
50:5,8,11,25	99:4,12,17	173:17 174:4,6	119:4 131:10	25:11 43:5,6
51:8,13,16,24	101:16 102:19	174:22 175:1,5	160:7 163:6	45:5 70:14
52:21,23 53:1	103:4,20,23,25	175:12 176:7	199:6 210:9	81:21,22 125:4
53:4,8,11,15	104:24 105:1,9	177:11 178:14	248:22	188:11 189:8
53:18,23 54:1	105:13 106:11	178:18,20	<b>oneyear</b> 152:21	214:22 220:1
54:4,10,16,19	106:21 107:7	179:25 180:21	<b>ongoing</b> 227:10	234:24
54:23 55:3,10	108:11 111:14	180:24 181:22	227:12	<b>ordered</b> 36:24
55:12,15,17,20	111:25 112:9	182:6,11,17	<b>onset</b> 216:7	<b>orders</b> 43:11,12
56:5,17,18,23	112:14,20,22	184:3,9,12	<b>ooo</b> 7:3	44:2,4,9 81:4
57:2,4,15,20	113:15,21	185:7 186:6	<b>open</b> 19:17	<b>organ</b> 63:2
57:24 58:3,6,9	114:5,10 115:3	190:12 199:18	59:15	142:3 190:14
58:14,22 59:3	116:24 117:2	208:15 216:2	<b>opened</b> 118:10	217:17
59:12,18,21	117:24 118:19	220:24 221:13	125:3	<b>organization</b>
60:7,13,22	118:25 119:4	223:20 225:24	<b>operate</b> 144:25	100:24 187:2
61:25 62:13,17	119:16,19	228:6 233:13	<b>operates</b> 211:16	<b>organizations</b>
63:6,12,14	121:6,9,13,24	238:18 241:7	<b>operating</b>	124:20 191:18
64:3,14 65:7,9	122:17,23	241:21 242:5	187:19 198:24	<b>organs</b> 12:1
65:16,19 66:11	123:5 124:10	242:18 246:13	<b>operation</b>	<b>original</b> 19:5
66:17,20,24	126:7,11	247:2,20 248:3	239:21	29:15 36:1
67:20,23 68:3	127:13,16,19	248:10,19	<b>operations</b>	257:12
68:9,15,23	128:14 130:7	249:12,15,19	148:1,10	<b>orlando</b> 126:4
69:2,12 70:11	131:15,20	250:16,20,24	<b>opinion</b> 20:24	126:12
70:22 71:6,15	132:13 133:23	251:4,9,11,16	24:24,25 27:23	<b>otoe</b> 256:3
71:18,23 72:5	136:17,25	252:2,9 253:5	97:17 109:22	<b>outcomes</b>
72:10,14,17,22	137:10 138:5	253:14	109:25,25	202:15 224:6
72:25 73:18	139:8,15	<b>old</b> 18:14,21	178:11 193:6	<b>outflow</b> 115:1
74:13,23 75:2	140:17 141:8	19:9 27:15	210:25 234:11	<b>outreach</b> 59:14
75:4,21,25	142:18 143:13	51:2,3 57:1	234:12,14,20	<b>outside</b> 32:21
76:3,20 77:22	144:2,7 145:2	81:16	240:1,23 241:1	47:12 87:6
78:8,13,19,23	145:8 146:7,12	<b>older</b> 19:6 51:6	246:2 252:19	<b>overactive</b> 55:18
79:1,5,7,17,21	146:23 147:9	217:4 222:1	253:17	<b>overall</b> 195:13
79:24 80:17,20	147:12,25	248:22,24	<b>opinions</b> 15:16	200:22 205:12
80:22 81:4,6	148:17 149:17	254:5	15:21 16:1	217:21 220:24
81:17 82:6,13	152:14,24	<b>oldest</b> 118:13	25:8,9,13 49:6	229:8 234:24

Michael P. Woods, M.D.

Page 283

246:6	63:20 88:5,6,9	57:19 58:2	<b>pathologists</b>	237:20 238:14
<b>overbroad</b> 45:19	89:15 118:2,3	72:1 88:7,8,22	90:22	240:21 244:1
97:9 98:11	121:14 123:24	100:13 105:10	<b>pathology</b> 90:15	250:11,14
<b>overhead</b> 227:8	124:6 125:17	105:11,25	90:19,21	251:4 253:6
<b>overlap</b> 72:23	125:21 127:13	106:14,16,17	<b>pathway</b> 212:16	<b>patrick</b> 7:10
74:1	127:16,19	128:5 149:10	<b>patient</b> 11:21	<b>paul</b> 4:15,17
<b>overlying</b>	134:2 137:14	151:23 152:4,9	25:10 45:3	61:9,10 64:20
228:19	225:25 226:2,3	152:12 165:16	46:6,13 79:25	<b>paused</b> 227:23
<b>overwhelming</b>	226:12 247:3	216:6 228:15	81:8,12 83:9	<b>pay</b> 36:13 39:15
70:4	<b>pain</b> 9:21 13:13	239:19	92:23 93:10	55:5 73:12
<b>overwhelmingly</b>	139:14 143:2,3	<b>partially</b> 180:14	106:12 107:11	87:12 88:3,11
246:11	143:6,21 149:6	<b>participate</b>	107:15,18,21	88:14,22
<b>oxidation</b> 176:8	149:9 160:20	133:9	107:24 139:19	121:12 124:2,4
<b>oxley</b> 1:15	160:22,23,24	<b>participated</b>	140:20 141:8	124:5 131:15
<b>P</b>		62:9,22	141:24 142:2	131:18
<b>p</b> 1:23 3:5 7:2,4	161:7,11,14,15	<b>particular</b>	143:8,10,16	<b>paying</b> 226:10
137:7,7 174:11	161:18,24	104:10 188:15	146:14 149:8	<b>payments</b> 57:10
174:11 225:9,9	162:1,5,9,11	205:8 209:4	58:20 60:10	58:20 60:10
255:16 256:6	162:23 163:2	<b>particularly</b>	87:21,23 118:8	87:21,23 118:8
259:8	163:13,19,20	200:6 229:10	158:17 159:1	<b>pelvic</b> 1:3 29:15
<b>pa</b> 59:22	164:8,15	241:11	176:15 178:21	35:22,23 62:24
<b>package</b> 19:17	174:19,20	<b>parties</b> 188:12	196:19 204:14	63:2 79:21
176:6	177:3,23	189:9	205:9,13,25	82:19 86:2,5
<b>page</b> 5:2 6:1 9:6	197:10 200:1,8	<b>partner</b> 135:1,7	212:11,13	86:23 89:13,25
9:8 24:3,5	200:11,12,14	139:6	215:24 217:15	101:20 102:6
48:16 56:13	200:19 208:19	<b>partners</b> 59:18	220:17 224:18	103:13 127:1
104:1 138:1	228:12 238:25	59:24	243:14,23	129:25 139:13
154:11 176:1,3	<b>palva</b> 249:1,4	<b>parts</b> 160:22	251:17	190:14 217:16
176:4 180:5,7	<b>paper</b> 7:17	165:11	<b>patients</b> 11:20	<b>pelvis</b> 102:18
189:8 190:12	147:5 161:3	<b>party</b> 80:9	45:9 47:11	104:8 143:21
193:15 203:11	172:14 201:9	256:18	83:3,4 132:22	<b>pelvises</b> 95:3
203:13,17	201:12 217:8	<b>pass</b> 155:12	133:3,7 140:25	<b>penalties</b> 81:23
205:3,14	220:17 222:3	<b>passage</b> 41:9	142:15,18	<b>pending</b> 55:23
217:13 223:22	244:17,18	<b>passed</b> 34:9	143:1,6,15	<b>penetration</b>
223:24 227:19	<b>papers</b> 30:3	40:23 41:10	144:5,10,10,17	143:19,20
228:2 231:17	177:3,12 178:4	82:17	144:25 145:16	<b>pennsylvania</b>
233:7 237:11	178:7 187:12	<b>paragraph</b>	151:22 158:25	4:12
248:18 254:5	223:24 225:18	230:25	160:23 176:25	<b>people</b> 41:3
258:3 260:2	228:1 233:7	<b>patent</b> 95:6	193:1 194:20	46:11 84:25
<b>pages</b> 9:8 214:24	239:1	<b>patented</b> 94:18	196:1,23 197:6	162:8 172:1
222:19 256:11	<b>paralegals</b> 69:6	<b>pathological</b>	204:2,11,19	177:22 214:19
259:3	142:1	91:16	207:8 211:19	250:1
<b>paid</b> 33:4,11,14	<b>pardon</b> 97:25	<b>pathologist</b>	215:20 216:13	<b>percent</b> 9:15
33:18,21,24	<b>parkway</b> 4:15	90:23 91:19,23	217:19,24	12:4,5 40:15
35:10,12 46:22	<b>part</b> 29:24 31:5	92:4,10 175:9	220:1,7,20	139:5,5 140:9
			223:1,12	141:12 144:4,8
			228:11 235:14	

Michael P. Woods, M.D.

Page 284

144:18 145:11	<b>person</b> 80:6	<b>physiologic</b>	218:1 228:22	194:10
145:12 146:8	<b>personal</b> 34:16	101:18 102:10	233:9,10 241:9	<b>portion</b> 88:11,24
146:10,13	56:2 158:1	102:17 104:25	<b>plane</b> 226:15	<b>position</b> 59:2,6
148:18 161:11	160:15 163:16	105:3	<b>planes</b> 168:15	151:7,14 154:9
161:12,12,16	201:1 208:13	<b>physiological</b>	<b>plastic</b> 176:16	154:24 213:17
161:16,17	210:4	101:19 102:5	231:5	<b>positiondepen...</b>
162:23,24,25	<b>personally</b> 34:13	104:6 106:8	<b>play</b> 107:4	224:13
163:1,3,3,4,5	135:22 155:25	<b>pi</b> 62:12	<b>player</b> 250:8	<b>positions</b> 54:8
198:23 199:1,2	171:3 249:11	<b>piece</b> 7:17 71:13	<b>please</b> 7:9 20:25	186:19
199:3,16	<b>personnel</b> 98:23	147:5 166:21	150:25 156:18	<b>positive</b> 23:24
200:11,11,13	<b>perspective</b>	176:16	176:3 185:12	47:3 106:10
200:13,14,15	140:20	<b>pile</b> 151:10	185:13 208:1	<b>possibility</b>
201:22,23,23	<b>pertain</b> 189:22	<b>pitchers</b> 214:19	221:9,10 257:3	179:23 202:18
202:2 205:25	<b>pertaining</b> 3:8	<b>place</b> 17:10	257:8	230:17
223:10,11,12	<b>pertinent</b> 54:6	19:19 20:20	<b>plus</b> 16:13 17:22	<b>possible</b> 58:16
224:18 237:12	<b>petersburg</b>	32:9,12 41:1	35:21	58:17 60:7
237:16,20	123:15	44:23 46:4	<b>pma</b> 43:9	176:21
238:1,3,4,6,11	<b>petersen</b> 3:9	104:9 108:4	<b>point</b> 10:8	<b>post</b> 89:13
<b>percentage</b>	256:4,23	130:19 155:13	111:20 137:6	111:23 112:1
11:16 162:20	<b>petros</b> 30:5 35:9	155:14 212:11	142:10 164:8	112:16 173:2
179:22 191:1	35:11,12	212:12 256:12	164:13,18	<b>postop</b> 141:3
<b>perform</b> 18:1	209:17	256:20	210:10 231:7	<b>postoperative</b>
139:9,10,11,11	<b>ph</b> 1:24 33:1	<b>placed</b> 16:10	163:19 174:15	163:19 174:15
139:13,15,21	78:24 79:1,7	17:11,17,21	174:19	<b>postoperatively</b>
140:3 142:3	173:18 185:7	18:4 19:12,24	156:15 157:2,4	156:15 157:2,4
237:22	<b>phase</b> 84:11	20:15 21:8	194:20 197:1	194:20 197:1
<b>performed</b>	130:14,14	22:25 40:22	216:4 239:19	216:4 239:19
139:16,23	<b>phenomenal</b>	108:10,12	<b>potential</b> 109:20	<b>potential</b> 109:20
143:12 144:21	214:19,20	143:17 156:9	171:16 196:5	171:16 196:5
154:13,15	237:18	157:22,25	<b>powerpoint</b> 5:15	<b>powerpoint</b> 5:15
164:4 246:18	<b>phoenix</b> 123:5	218:9 221:17	62:5	62:5
<b>performing</b>	<b>phone</b> 52:24,25	<b>placement</b> 18:2	<b>powerpoints</b>	<b>powerpoints</b>
138:13,20	53:2 81:11	106:19 159:5	60:17	60:17
139:25	<b>physician</b> 45:4	<b>placements</b> 18:6	<b>practice</b> 54:7	<b>practice</b> 54:7
<b>perinatologist</b>	103:13,13	<b>placing</b> 32:8	59:9 82:24,25	59:9 82:24,25
89:19	150:16 158:7,9	39:16 108:15	84:23 96:18	84:23 96:18
<b>period</b> 124:24	160:5,9,13	<b>plain</b> 136:9	125:3 139:1,2	125:3 139:1,2
179:13 246:23	<b>physicians</b>	<b>plaintiff</b> 55:22	177:19 194:14	177:19 194:14
<b>perioperative</b>	24:11,13,14,20	<b>plaintiffs</b> 4:3	227:8	227:8
216:1,3	25:3,7,13,19	49:17 70:23	<b>pore</b> 18:9 42:13	<b>practitioner</b>
<b>perioperatively</b>	25:23 81:15	71:10,16,24	184:12,14,25	59:21
216:9	109:10 128:13	72:6,12,18,19	194:3,7 231:12	<b>pre2007</b> 249:2
<b>periurethral</b>	128:19 134:2	73:1,15 74:15	232:22 233:3	<b>preceptorships</b>
28:10 35:21	142:12 150:12	74:25 75:5	131:25	131:25
<b>permanent</b>	156:22 168:5	76:4,12 77:14	<b>pores</b> 166:2	<b>precise</b> 95:5,18
186:7,9,10	168:21 169:18	189:25 216:23	167:4,19	

<b>predominate</b> 194:14	<b>prior</b> 13:20 14:8 14:16 15:9 29:18 33:18	198:17 216:16 <b>proceed</b> 8:6 43:2 142:10	244:19 <b>professionally</b> 80:23,24	84:22 108:10 157:22,25 242:11
<b>preop</b> 163:3,5	50:12 64:21 132:22 245:8	<b>proceedings</b> 256:15	<b>profile</b> 184:24 229:12	<b>properties</b> 194:2 212:10
<b>preparation</b> 65:20	<b>priorly</b> 138:11	<b>process</b> 29:25 84:9 98:15 243:18	<b>profound</b> 204:25	<b>propounded</b> 259:5
<b>prepare</b> 67:2,11	<b>private</b> 81:15	<b>produced</b> 105:25 106:2	<b>program</b> 83:7 <b>programs</b> 82:11 131:3	<b>proregion</b> 33:1
<b>preparing</b> 53:20	<b>privileges</b> 81:9 83:1	<b>producing</b> 249:18	<b>project</b> 180:15 181:3,15,17,20	<b>prosima</b> 43:18 46:4 128:24 129:22
<b>preprocedure</b> 163:2	<b>privy</b> 44:21 136:1	<b>product</b> 11:24 16:5 22:12,14 22:22 23:11,20 36:14 37:12	181:22,23,24 182:4,18,23,25 183:3,7 184:6 184:8,10 185:1	<b>protocol</b> 238:2
<b>prescription</b> 94:10	<b>probably</b> 16:19 17:11 42:20	<b>problems</b> 132:11 172:2 243:15 243:21	<b>projects</b> 180:20 <b>prolapse</b> 11:7 63:2 141:21 142:4 190:14 199:24 217:17	<b>protrusion</b> 239:3
<b>present</b> 17:13 24:11 36:19 47:6,8 190:20 193:2 213:7	52:16 55:1 57:8 66:21	133:10 188:18 203:1 250:21 253:10	<b>prolene</b> 18:9,13 18:20 29:14,18	<b>prove</b> 160:3
<b>presentation</b> 89:20,21 103:1 103:2,16,20 159:1	70:20,21 105:7 105:25 107:9 124:18 125:1 131:12 136:19	<b>products</b> 1:3 23:1,14 28:7 35:15 36:24	29:18,24 30:1 114:11 166:3 166:11,12,16	<b>provide</b> 25:12 62:17,20 69:8 69:12,13 75:16
<b>presentations</b> 31:10 60:17 61:6 62:5 132:4	137:2 141:11 147:13 159:12 202:17 216:15 219:18 226:23	37:25 38:8 43:22,24 44:6 44:11 62:24	167:5,25 169:23 170:5,7 170:20 171:7	<b>provided</b> 46:25 49:5,16 50:17 53:4 67:18,19
<b>presented</b> 72:4 106:15 145:13 244:11,12,14	<b>problem</b> 132:11 172:2 243:15 243:21	43:6 85:10,15 63:6 85:10,15 63:6 85:10,15 112:12 127:1	184:15 191:12 207:6 209:19 210:7	69:14,15 113:9 113:21 173:8
<b>presently</b> 92:24	<b>problems</b> 172:5 197:9 238:23 239:9,12,17,22	128:11 129:7,9 130:5,5,7	<b>prolift</b> 43:17,20 46:18,20 129:1 129:3 142:7	<b>pse</b> 105:22 106:1
<b>pretty</b> 37:14 121:12	<b>procedure</b> 3:7 6:7 10:5,23	132:1,10,16,19 132:25 135:12	<b>promise</b> 117:6 <b>promote</b> 127:1 128:2,8 194:11	<b>public</b> 3:9 256:5 256:24 259:18
<b>prevent</b> 138:17 138:23 176:7	89:10 90:3 103:14 106:22	135:16,21 143:25 209:12	<b>promoted</b> 44:12 127:21	<b>publication</b> 86:18 244:18
<b>preventia</b> 99:21 99:22	124:20 130:24 138:15,21	143:25 209:12 143:25 209:12 143:25 209:12	127:21	<b>publications</b> 51:3
<b>prevention</b> 31:22	139:21,24	151:8,15,24	<b>promoting</b> 128:11	<b>published</b> 90:2,5 162:16 232:1 244:9,14
<b>previous</b> 53:11	195:18 204:25	152:7	<b>propensity</b> 193:23	<b>pubmed</b> 69:25
<b>previously</b> 31:19	209:9 216:13	<b>prof</b> 116:10,12 225:20	<b>proper</b> 155:10	<b>pubovaginal</b> 90:6 139:15
<b>primarily</b> 234:17	220:8 222:13	<b>professional</b> 60:16 84:20	<b>properly</b> 25:11	198:25 199:1,2 199:5,14,16 217:5 246:6
<b>primary</b> 45:7,11 45:17 46:4 84:8 164:25 165:14 189:9	228:12,14 243:5	92:21 131:7	<b>pull</b> 70:1 71:18 73:14 101:22	161:20 163:11
<b>print</b> 61:13	<b>procedures</b> 12:13 13:7	171:20 213:18	<b>properly</b> 155:10	106:21 154:11
<b>printed</b> 72:17 74:23	139:11 145:18 154:13,15 159:12 197:25	229:17 242:5	<b>properly</b> 25:11	155:19 161:19

168:18 173:24	8:2 11:17	<b>R</b>	205:16 208:11	<b>reason</b> 43:3
174:8,25	14:13 15:4	<b>r</b> 1:5 7:2 258:1,1	208:18 211:23	257:5 258:5,7
185:11,12	19:2 21:1	<b>raised</b> 233:9	211:24 219:25	258:9,11,13,15
<b>pulled</b> 43:4	25:18 32:7,14	<b>ran</b> 97:2	221:1,16,21,21	258:17,19,21
175:21 222:2	39:25 40:5,10	<b>randomized</b>	221:24 222:5	258:23,25
<b>pulling</b> 17:2	41:16 72:25	6:11 74:6 97:5	236:8 238:8,20	<b>reasonable</b>
102:16	74:19 111:4	109:23 111:11	254:6	136:13 145:7
<b>pullout</b> 5:15	113:7 114:25	111:14 141:18	<b>ray</b> 222:4	<b>reasonable</b> ness
102:9,11,14	116:21 127:5	149:13 160:3	<b>rct</b> 152:22 153:1	193:7
104:1,14 105:3	144:24 148:23	164:13 165:4	153:5 164:18	<b>reasonably</b>
105:23 106:20	156:18 163:11	173:3,21	164:25 165:10	149:3 188:5,19
107:4	163:15 170:3	176:21 180:9	165:14 193:4	189:12 192:19
<b>purchase</b> 23:11	170:11,17,19	189:18 195:15	204:8	<b>reasons</b> 204:4
<b>purchasing</b>	170:20 171:6	205:4 214:21	<b>rcts</b> 150:20	204:24 216:12
22:18,20,22	171:13 180:21	222:7,10,15	152:19 153:2,3	<b>recall</b> 12:21
36:6,23 37:2,5	180:22 188:18	236:20 237:17	160:21 193:3	13:17 22:17
37:7,9 134:6	208:3 225:16	240:3	216:5 246:10	25:22 35:8
<b>pure</b> 99:19	226:2,3,24	<b>range</b> 101:19	248:17,20	38:23 41:2
<b>purpose</b> 100:4	234:13 237:10	141:20 218:15	<b>reaction</b> 197:6	43:15 44:10
<b>pursuant</b> 3:6	241:7 242:21	<b>rank</b> 234:15	239:3	50:7,10 57:16
<b>put</b> 11:17 37:25	254:10,16	<b>rapidly</b> 77:12	<b>read</b> 30:19 70:8	57:22 58:8,15
67:14 68:19	<b>questionnaires</b>	230:22	71:14 76:24	58:17 71:8
69:17 93:16	140:25 197:11	<b>rate</b> 9:15 10:6	133:18 144:24	76:19 78:21
106:25 133:2	<b>questions</b> 15:4	32:16 140:9,14	163:16 166:15	79:9,10,16
141:16 145:19	49:19 51:22	141:9 144:3,18	166:19 175:12	80:11 83:8
148:17 155:3	52:7,11 117:1	145:10 146:8	180:7 188:17	91:5,22 92:11
155:19 171:3	122:23 126:6	146:13 147:21	209:15 228:1	94:8 96:21
213:12 220:7	126:11 162:22	148:19,19	233:14 236:24	99:6 100:8,19
220:16	170:19 187:8	164:14,19	237:24 239:4	100:20 105:11
<b>putnam</b> 78:17	187:11 210:20	171:16 190:25	239:15 257:3	107:9 113:18
<b>putting</b> 37:12	218:2 222:18	199:14 201:25	259:3	113:19,19
158:21 177:19	225:24 234:6	205:12,25	<b>reading</b> 71:3	114:4 121:23
183:19	241:10 242:18	207:18,19	138:12 193:22	126:13 127:8,9
<b>pyramid</b> 70:6	246:16 253:14	210:3,19	231:24	129:11 131:14
234:16	255:15 259:4	215:22 223:10	<b>real</b> 98:24 99:9	132:14,17,20
<b>Q</b>		<b>quick</b> 48:3 74:22	<b>really</b> 11:17	134:7,9 139:25
<b>qbt</b> 162:16	101:24 174:10	101:24 174:10	19:16,17 24:13	158:11 180:1
<b>qualifier</b> 103:12	237:10	231:1 237:20	30:12 36:11,12	181:20,24
<b>qualify</b> 41:24	<b>quickly</b> 41:10	238:3,11	36:12 39:23	182:24 183:2,5
<b>quality</b> 92:23,24	<b>quit</b> 44:1,15,18	<b>rates</b> 6:4 9:12,16	84:21 109:5	183:8,15 185:2
96:15 109:21	84:23	21:19,22,24	121:16 143:14	185:4,6 202:20
113:13 141:2	<b>quite</b> 37:23,24	161:2 165:6	144:14 175:6	225:14 234:6
165:12 178:16	58:17 95:14	190:23 197:24	176:19 204:4	242:21 248:1
192:16 217:6	167:16	199:24 200:1	212:8 222:8	<b>receipt</b> 257:14
<b>question</b> 7:24,25	<b>quote</b> 163:7	200:16 201:22	<b>rearrangement</b>	<b>receipts</b> 119:7
	240:21	202:1 203:25	194:6	<b>receive</b> 58:20
		204:6,10 205:9		

Michael P. Woods, M.D.

Page 287

87:23	246:14	<b>regional</b> 18:4	236:3	145:10 146:8
<b>received</b> 57:10	<b>redos</b> 216:15	23:4 36:21	<b>reliable</b> 193:6	146:13 148:19
60:10 74:25	<b>reduce</b> 180:12	<b>registries</b> 45:4	202:23 207:13	<b>reoperations</b>
87:21 118:9	<b>reduced</b> 228:16	173:23 174:1	214:24 221:1	147:10 246:20
<b>recess</b> 48:7	256:9	222:19,20	221:15 228:24	<b>rep</b> 37:17,18,19
102:2 137:7	<b>refer</b> 8:20 65:6	<b>registry</b> 174:4,6	231:19 232:6	37:21,24 38:5
174:11 225:9	103:25	174:24 222:21	233:18 235:12	<b>repair</b> 1:3 5:22
<b>recognize</b> 76:21	<b>reference</b> 72:20	222:24 223:5	246:9	45:7,11,17
76:23 115:16	154:13 155:3	<b>regulation</b> 97:20	<b>reliance</b> 50:1	46:4,10,12
117:11,14	179:16 185:7	<b>regulations</b>	67:5,7,8,11	141:22 142:1
<b>recognized</b> 12:2	<b>referenced</b> 8:23	96:12,15	68:20 69:2	186:6
<b>recollection</b>	223:21	<b>regulatory</b>	70:19 71:11	<b>repairs</b> 12:24
51:25 52:12	<b>referencing</b>	97:14	72:6,11,19	29:14 139:10
78:22 179:20	197:22	<b>reimbursed</b>	73:2,20 75:5	142:4 187:20
220:19	<b>referred</b> 68:25	226:7,16	77:10,19	<b>repeat</b> 20:25
<b>recommend</b>	143:11 144:25	227:11,12	105:10,12	70:15 156:18
133:7 204:21	180:5	<b>reinforce</b> 245:7	134:14 182:12	221:9
<b>recommendati...</b>	<b>referring</b> 67:4	<b>reinforces</b>	183:11 233:22	<b>repetitions</b>
153:8 192:15	224:1	202:14	<b>relied</b> 29:23	49:13
<b>recommended</b>	<b>refers</b> 134:16,25	<b>relate</b> 7:18	67:16 198:8	<b>rephrase</b> 207:25
168:25	<b>refined</b> 8:12	12:10 21:24	234:17 236:24	<b>replicated</b> 29:2
<b>recommends</b>	<b>reflect</b> 62:4	106:6	<b>relieved</b> 228:12	33:16 133:13
48:1	116:22	<b>related</b> 10:13	<b>rely</b> 15:19,25	133:15
<b>reconstruction</b>	<b>reflected</b> 134:8	13:2 62:23	<b>relying</b> 74:18	<b>report</b> 5:14 24:3
129:25	<b>reflection</b>	68:16 71:20,22	<b>remaining</b>	28:19 56:8
<b>reconstructive</b>	256:15	71:25 72:2	217:19	64:25 65:14,17
82:20	<b>reflects</b> 113:14	79:18 93:12	<b>remember</b> 49:17	65:19,22 66:18
<b>record</b> 7:9 20:11	148:21	134:5 142:16	51:11 57:6	66:21 73:22
20:11 45:22	<b>regard</b> 32:14	142:19 143:6,9	60:2,6 78:17	75:5 76:18,24
53:25 55:7	188:12 190:16	180:12 181:9	79:25 88:10	113:16 137:22
62:3 65:5 69:6	194:23 195:13	182:12	100:24 113:17	138:8 140:8,11
102:4 138:3,4	196:11 198:15	<b>relates</b> 1:5	145:15 167:14	148:18,24
138:6 151:8	201:19 203:14	<b>relationship</b>	181:13 183:17	155:6 164:7
190:11 220:17	206:1 208:16	132:21 133:20	183:18,19,20	170:4 171:19
249:18,20	209:16,25	<b>relative</b> 256:18	226:18 241:19	174:2 176:1
<b>records</b> 58:18	211:22 214:3,8	<b>release</b> 217:15	<b>removal</b> 228:13	179:17,25
60:10 118:12	219:13 221:15	243:2	<b>remove</b> 175:25	182:15 185:8
118:25 147:14	223:7 231:19	<b>released</b> 97:8	244:8	198:2 200:1
148:13	233:8,18 236:4	<b>relevance</b> 135:2	<b>removed</b> 149:5	203:12,13
<b>recrossexamin...</b>	238:21 240:11	<b>relevancy</b> 30:21	168:9 172:9	205:3,14
5:10 253:15	244:25	31:8,12	<b>removing</b> 168:6	214:24 221:7
<b>rectum</b> 34:9	<b>regarding</b> 29:13	<b>relevant</b> 29:14	168:22 169:4	222:19 223:22
<b>rectus</b> 186:10	31:11 185:19	70:2 187:14,17	169:10 242:20	224:6 231:17
<b>recurrence</b> 45:9	<b>regardless</b>	187:19 188:3,6	<b>rendering</b> 16:1	233:8 241:1
140:17	252:19 253:18	211:3 215:1	<b>reoperation</b>	244:17 248:18
<b>redirect</b> 5:9	<b>regency</b> 3:11	233:24,25	<b>reported</b> 47:3	

Michael P. Woods, M.D.

Page 288

115:5 162:1	<b>respect</b> 25:13	41:14,22 42:4	239:13 240:8	71:1 72:9,20
222:25	69:20 86:3	68:17 99:5	240:12,19	72:24 73:18,21
<b>reporter</b> 5:5	<b>respected</b> 86:1	101:6 104:4	241:2 242:6,11	75:21 76:8
86:16 103:7	<b>respectively</b>	112:10,18,24	243:3,19	78:7 90:21
128:5 253:13	191:1	113:4,11 114:1	244:20 245:18	99:6,13 100:9
<b>reportim</b> 253:24	<b>responded</b> 149:9	114:7,12	246:11 247:21	113:3 133:18
<b>reporting</b>	<b>response</b> 75:15	127:21 128:16	248:4,8 254:20	134:4,10,13
162:20	162:19 194:4	128:20 142:19	<b>retropubics</b>	150:19 160:19
<b>reports</b> 70:23	<b>responses</b> 44:8	142:22 143:7	19:15 20:20	167:11 172:4
71:2,10,16,25	<b>responsible</b>	143:16,23	<b>return</b> 198:24	173:8 181:11
72:7,12,19	36:24 37:12	144:17 145:11	257:12	183:8,14,21
73:2,16,18,19	<b>responsive</b>	145:20,22	<b>returned</b> 226:5	185:25 187:12
74:15 75:10	48:22	149:15 150:7	<b>reversals</b> 207:7	191:24 201:12
76:5,12 77:2,9	<b>restate</b> 45:15	150:21 153:4	<b>review</b> 14:23	203:7 236:3
77:15 164:10	221:11	154:2,20	29:17 44:4,7	<b>reviewing</b> 50:20
178:25 179:2	<b>restrictions</b> 82:1	155:11,12,24	48:15 50:5,8	51:4 70:18
233:11,14	<b>result</b> 227:24	156:22 159:8	50:11 51:1	71:9 76:3,8,11
235:4 239:2	228:18,18	159:20 161:10	55:7 65:19	89:25 181:13
<b>represented</b>	<b>resultant</b> 194:4	164:16,20	67:1 70:25	183:23 184:1
79:14 80:6	194:12	165:19 166:13	71:6,15,22	<b>reviews</b> 35:1
<b>reproducibility</b>	<b>resulting</b> 239:20	178:21 179:8	72:5,12,13,15	51:1 70:1,14
214:18	<b>results</b> 6:11	184:15 187:18	73:8,16 74:7	141:19 165:5
<b>reproducible</b>	30:15 31:1	187:22,24	74:15,20 76:1	173:5,22
214:21	105:6 107:7	188:25 189:2,5	76:18 77:2,11	189:19 193:3,4
<b>reps</b> 129:15	130:21 131:1	195:5,16 198:2	77:14,18 99:4	193:5 195:7,8
<b>request</b> 23:16	141:6 162:20	198:17,22,25	101:5 103:6,9	207:20
48:15 105:14	183:7 223:6	199:2 200:6,23	113:8 161:22	<b>revised</b> 149:5
<b>requested</b> 23:13	232:1 237:9,24	201:6 203:16	164:3 166:20	161:4,5
<b>required</b> 98:6	237:25 238:15	203:19 204:1	172:15,19,19	<b>revision</b> 91:25
217:15	238:16	204:16 206:24	174:23 175:1	144:21 145:3
<b>requiring</b> 9:23	<b>retention</b> 12:17	207:15 208:23	181:1,1,6,9	<b>revisions</b> 143:22
9:24	114:16 141:6	209:4 210:14	182:9,9,17,20	144:9 246:25
<b>research</b> 84:25	142:24 239:21	212:12 213:9	183:6,11	<b>revvoid</b> 224:14
85:16 86:13,17	239:23	217:3,22	187:17 191:25	<b>rewarding</b> 205:1
86:24 90:8	<b>retropubic</b> 6:7	218:11,12,18	192:11,13,14	<b>rid</b> 60:13
91:8,11,15	7:19 8:10,13	218:24 219:14	192:15 193:14	<b>ridgeland</b> 4:16
97:7	10:21 11:18	219:22 220:2	193:15 197:20	<b>right</b> 13:9 14:14
<b>reserved</b> 255:18	12:10,13 13:2	221:2,17	197:21 198:12	16:25 17:7
<b>residencies</b>	13:23 16:5,9	222:11,16	198:15 200:25	19:21 26:8
245:13	16:11,18,21	223:9 224:22	<b>reviewed</b> 14:6	27:21 31:2
<b>residency</b> 29:10	17:6,10,21	227:1 229:13	14:20 25:24	54:19 58:21
30:14 81:18	18:1,10 19:6	229:18,24	26:9 27:4,10	60:25 62:5
222:7	19:11,14,24	230:6,12,16	30:19 31:7,10	68:9 70:17
<b>residuals</b> 224:10	20:15 22:16	233:23 234:1,1	31:14 34:18	73:3 74:8,23
<b>resolved</b> 239:23	34:20 35:17,25	236:13,16,22	43:10,12,15	81:24 84:4
<b>resources</b> 59:7	36:5 40:18	237:5 238:22	49:14,20 70:22	89:19 90:9

Michael P. Woods, M.D.

Page 289

99:14 100:18	<b>rosenzweig</b>	245:22	222:21	26:16 29:11
117:15 136:11	50:15,16	<b>sales</b> 37:17,18	<b>scientific</b> 187:23	49:25 105:19
136:22 144:3	233:12	37:19,21 38:5	189:9 194:23	107:2 108:10
146:1 154:5	<b>ross</b> 249:4	57:14 58:12	202:23 207:14	110:4 114:25
158:13 167:9	<b>round</b> 126:24	129:12,15	214:25 232:6	118:23 133:23
169:14 174:2	<b>rounds</b> 89:14	132:3	233:18 235:12	137:22 141:2
177:24 182:13	<b>route</b> 232:4	<b>salt</b> 125:19	<b>scientifically</b>	142:8,25
182:15 183:18	<b>rule</b> 5:14	<b>san</b> 123:9 126:2	221:1,14	143:14,15
187:3,5 188:22	<b>rules</b> 3:6	<b>satisfaction</b>	228:24	145:2 151:17
234:13 238:16	<b>run</b> 61:3 124:8	140:20 141:9	<b>scientist</b> 214:14	154:25 158:17
254:15,25	131:24 216:10	204:14 205:9	214:15	161:23 162:5
255:2,10	225:1	205:13,16,25	<b>scion</b> 181:15,17	168:12 172:1
<b>rigidity</b> 228:15	<b>running</b> 107:25	238:6,11	181:21 185:1	175:2,15
<b>rings</b> 100:17	128:2,7 146:25	<b>satisfied</b> 223:13	<b>scissors</b> 109:14	177:13 180:4
<b>rinne</b> 249:1,4	219:2,5	<b>saw</b> 33:15 34:12	<b>scope</b> 96:16	187:9 197:12
<b>risk</b> 12:3,12,22	<b>rural</b> 59:14	85:19 127:5	<b>scores</b> 47:11	199:24 202:14
13:7 93:15	<hr/>	151:12 172:22	<b>scrutiny</b> 43:7	215:14 216:15
110:14 157:17	<b>S</b>	189:25 212:20	<b>seal</b> 256:21	220:12 222:3
166:3,17	<b>s</b> 1:6 4:15 7:2	225:2 233:9,15	<b>sealed</b> 109:4	224:19 225:18
167:20 179:7	29:8 79:14	<b>saying</b> 27:22	<b>search</b> 61:5	227:22,25
179:10 194:12	101:3	71:2,13 114:6	171:24	230:22 235:24
198:15 232:10	<b>sacrococpopexy</b>	172:15,19	<b>searches</b> 69:23	236:9 238:24
<b>risks</b> 10:12	46:11 109:13	177:16 179:21	69:25	238:25 247:5
11:12,23 12:9	141:23	231:5	<b>second</b> 29:10	255:1
12:24 13:1,20	<b>safe</b> 100:3	<b>says</b> 57:24 59:25	65:24 84:10	<b>seeing</b> 38:23
13:25 14:7,15	132:16 188:5	99:16 113:11	121:21 122:11	114:14 145:6
15:8 196:5	188:19 189:12	115:6 122:14	151:1 154:10	170:2 225:1
<b>rnr</b> 3:9 256:4	192:19 241:2	150:22 180:8	167:7	230:22 231:2
256:23	<b>safer</b> 243:14	183:17 189:8	<b>secondtolast</b>	239:8
<b>ro</b> 50:14	<b>safety</b> 14:10,22	190:13 191:6	227:19	<b>seen</b> 28:5 31:22
<b>road</b> 217:23	92:23 93:2,4	223:6 224:17	<b>section</b> 96:20	34:13,22,25
<b>robinson</b> 68:9	93:10 98:22	225:16 228:10	133:20 217:15	35:3,5,6 37:23
68:16	133:10 151:20	237:12,24	237:9,24	40:2,7,10
<b>robust</b> 211:24	152:17 164:25	238:19 239:2	238:16	48:12 101:13
<b>role</b> 94:25 107:4	165:6,15,16	<b>scandinavian</b>	<b>secur</b> 17:18 28:9	106:2 107:7
<b>roll</b> 157:18	173:20 184:24	29:4	41:15,20,22	109:16 111:8
<b>rolodex</b> 81:14	187:18 193:7	<b>scar</b> 11:25	43:13 46:23	113:7,10,13,15
<b>room</b> 198:24	195:23 200:22	<b>scarring</b> 245:17	47:4,7 62:10	113:16 114:10
<b>rope</b> 101:12	209:5 214:8	<b>scattered</b> 54:9	62:11,14 97:19	141:16 157:24
108:8	215:10 216:2,9	<b>schedule</b> 37:10	102:14 104:3	167:7 169:3
<b>roping</b> 108:10	217:9,21	38:9 48:16	106:18 129:8	172:4,9,21
232:10	224:22 229:12	81:14	130:19 227:20	175:18,20,23
<b>rosenblatt</b> 4:15	233:19 234:25	<b>schepleng</b> 2:18	228:12,14	176:14 177:19
4:17 61:11,14	236:10 237:7	<b>school</b> 85:23	<b>sedation</b> 18:8	177:23 178:2,4
64:20 67:4	238:21 240:11	90:21,25	<b>see</b> 19:21 21:18	178:7 179:19
75:13 116:12	240:18 241:17	<b>schraffordt</b>	24:5,6,20	190:6 202:23

Michael P. Woods, M.D.

Page 290

207:8,20 208:5	200:15,19	81:8 111:13	<b>simply</b> 170:19	10:13,17 11:1
208:21 212:1	231:20 232:3	170:23,24	171:6	11:11,14 12:14
214:6,10	<b>sgs</b> 141:20 173:5	171:1 195:16	<b>singh</b> 242:1	29:18,25 32:13
217:23 222:5	193:6 197:19	240:14	<b>single</b> 135:20	32:24 34:20
228:4,23,24	231:22	<b>showing</b> 110:14	254:19	42:18,22
<b>segment</b> 228:13	<b>share</b> 86:9	<b>shown</b> 140:12	<b>singleincision</b>	102:16 108:6
<b>selecting</b> 30:22	<b>shared</b> 72:8	225:12	6:9 42:18,21	139:11 143:16
<b>sell</b> 24:21	<b>shears</b> 2:3	<b>shows</b> 113:3,5	108:6 154:22	168:6,16,22
<b>sells</b> 112:12	<b>sheath</b> 212:13	149:19 175:17	155:1 241:23	172:10 178:22
<b>send</b> 75:14	212:17,21	203:24 207:11	241:25	186:2,11
175:8	213:1,5,7,14	235:13	<b>sir</b> 169:9	190:21 198:25
<b>sense</b> 31:3	230:9,11,19	<b>shrink</b> 112:23	<b>sister</b> 204:21	199:15 200:5
<b>sent</b> 73:15 75:8	231:5 232:9	113:2 114:8,22	<b>sit</b> 13:9 14:14	200:17,23
91:19 149:8	255:10	<b>shrinking</b> 115:1	18:19 20:16	220:8,9 221:22
<b>sentence</b> 138:11	<b>sheaths</b> 155:19	<b>shrinks</b> 113:4,12	21:13 38:20	232:4 241:23
<b>separate</b> 55:13	<b>sheet</b> 53:21	113:23 114:6	40:12 93:23	241:25 243:3
83:17 168:17	54:13,16	114:12,18	<b>slings</b> 8:16 17:17	
244:4	161:20 234:2	99:14 100:8,18	24:22 28:19	
<b>september</b> 53:14	257:7,9,12	<b>shy</b> 231:16	29:9 30:13	
53:15,19 54:14	259:6	109:1 111:7	31:21 43:14	
54:17,25 90:1	<b>sheets</b> 50:18	<b>sic</b> 17:7 58:2	121:13 146:17	
<b>sequelae</b> 5:22	53:23 54:18	<b>side</b> 87:24,24	146:20 163:10	
<b>serati</b> 201:10,10	<b>shelf</b> 37:13 38:8	141:25 244:7	170:7 173:7	
217:7	<b>shenandoah</b>	170:7 222:9	90:6 128:16	
<b>serially</b> 196:2	23:6 36:21,22	<b>sign</b> 239:2 257:8	138:14 139:15	
<b>series</b> 172:23,25	59:1 83:22	<b>signature</b> 65:13	142:16 144:20	
173:1 246:2	85:5 139:3	115:17 117:14	145:4,20,22,24	
<b>serve</b> 78:2	187:1	117:15 119:24	145:25 150:17	
<b>served</b> 92:21,22	<b>shes</b> 86:1,20	120:15 121:4	<b>sites</b> 63:1	151:15,21
133:5	247:9	255:18	<b>sitting</b> 176:16	152:18 154:19
<b>service</b> 81:11	<b>short</b> 195:25	<b>signed</b> 121:21	<b>situation</b> 42:5	154:22,25
147:19	<b>shorter</b> 97:5	122:5,17,18	45:2	155:2,9 160:6
<b>services</b> 83:24	<b>show</b> 35:1	<b>significance</b>	<b>situations</b> 44:24	168:9 169:5,10
84:3	111:25 112:3	237:16 238:20	<b>six</b> 83:25 160:20	177:20 199:5
<b>set</b> 124:12 125:2	112:16 113:1	239:6 254:15	160:25 161:25	200:2,3,8
125:8 256:9	113:19,20,22	<b>significant</b>	162:6 163:15	216:12,17,18
<b>setting</b> 32:6	160:2 164:24	171:5 207:7	163:20 179:14	216:24 217:5
216:3	177:8 178:23	210:19 213:19	<b>sixmonth</b> 47:9	219:6 223:14
<b>seven</b> 38:3,8	179:2 195:8,12	214:5 217:12	47:15	223:25 242:24
110:13 118:24	198:15 201:9	217:16 232:10	<b>size</b> 18:9 42:13	246:2,7
119:1,3,5	201:18 202:25	235:21	184:9,12,14,25	<b>slow</b> 224:13
121:18 249:8	203:22 208:15	<b>significantly</b>	194:3,8 208:25	<b>small</b> 37:6 95:5
249:12	209:24 211:21	204:12 210:3	<b>skim</b> 74:22	172:12,23
<b>sexual</b> 161:11,15	215:9 223:7	232:3	<b>skimmed</b> 70:9	173:1 179:11
161:16 162:22	232:9	<b>signs</b> 239:9	76:1 77:12	207:10
200:2,8,11,13	<b>showed</b> 35:19	<b>similar</b> 35:20	<b>slides</b> 90:21	<b>smaller</b> 231:12
		<b>simple</b> 11:17	103:8 116:10	<b>smith</b> 247:25
		39:23 145:18	116:13	248:4
		225:16	<b>sling</b> 5:24 10:10	<b>sneezing</b> 107:22

Michael P. Woods, M.D.

Page 291

<b>snell</b> 4:10,13 5:8 5:10 7:22 8:1,4 13:4 14:2 15:10 18:15,22 19:1 20:1,4,10 20:22 21:10,14 23:12 25:5 26:11,19,22 27:1 28:2 33:6 39:2,6,9,18 40:1,6 41:7,15 42:1 44:14 45:12,18,24 48:4 49:18 51:21,25 52:3 52:6,18 56:14 56:17 61:9,13 61:15,19 62:3 63:17 65:9 69:5 73:23 74:11 75:3,7 75:18 83:11 86:7 89:2 90:16 93:18 94:16 97:9 98:2,10 101:7 102:23 104:18 105:19,22 106:23 110:6 110:24 111:5 113:24 114:20 116:6,8,10,15 116:18,23,25 117:3,8 120:25 121:2 122:1,12 122:22 123:25 126:6,9 127:4 127:23 128:1,7 129:23 134:22 135:2 136:10 136:15 146:4,9 148:2,4,6 151:2,6 153:14 153:21 156:16 157:20 158:14 159:2,10 160:1	160:8,14 163:21,25 165:2,22 166:5 167:21 168:8 168:23 169:11 169:16 170:13 170:18 171:9 171:14 173:11 177:5,25 178:9 181:4 183:13 185:16,22 186:8 187:5,7 188:1,10 189:23 191:2 191:23 192:9 193:13 194:21 196:9,21 197:5 198:19 199:4 199:21 201:4 202:9,16 203:5 205:2,23 206:8 207:12 208:2,4 209:14,23 211:9 213:10 213:23 214:12 215:17 218:16 219:4,19 220:5 221:5,12 223:19 225:3,8 225:11 227:16 229:7,16 232:13,17,21 233:2 234:21 235:19 236:1 236:19 240:17 242:17 246:4 246:13 249:17 250:2,7 251:20 252:5,17,25 253:12,16 255:15 <b>snodgrass</b> 2:10 <b>snow</b> 4:10,14 <b>societies</b> 213:18 <b>society</b> 48:1 131:7,16,18,21	<b>society's</b> 153:7 <b>sold</b> 23:23 38:15 38:21 39:13,24 40:13 <b>solid</b> 97:14 <b>solo</b> 59:21 227:8 <b>somebody</b> 46:7 133:14 <b>someplace</b> 137:16 <b>somewhat</b> 230:19 <b>sondra</b> 3:9 256:4,23 <b>sonoma</b> 123:17 125:14 <b>sorry</b> 34:4 41:16 55:25 56:15 67:7 116:7 127:4,5 137:21 140:18 176:4 237:11 <b>sounds</b> 66:11 99:24 <b>southern</b> 1:1 127:10 <b>space</b> 156:11 257:6 <b>spacing</b> 155:13 155:14 156:1 159:4,18 <b>sparc</b> 144:14 <b>speak</b> 10:7 240:18 <b>speaker</b> 131:2 <b>speaking</b> 103:3 103:12,18 <b>special</b> 30:24 139:12 <b>specific</b> 8:13 25:23 27:9 93:20 123:22 186:3 187:21 220:22 <b>specifically</b>	23:17 99:7 103:25 105:2 106:16 107:10 118:16 126:13 127:1 142:11 142:14 150:8 152:20 165:10 179:4 197:9 233:11 245:18 <b>specified</b> 256:12 <b>speculation</b> 14:3 <b>spend</b> 54:3 70:17 71:9 76:3,11 167:16 131:6 230:24 <b>spreadsheet</b> 147:4 <b>sprout</b> 1:8 ss 256:2 <b>st</b> 123:15 <b>stable</b> 114:16 <b>staff</b> 57:14 58:13 129:12 <b>stage</b> 35:22,22 <b>stamey</b> 138:15 138:20 <b>stand</b> 65:16 <b>standard</b> 32:1,9 32:12,18,21 44:23 45:10,16 46:3 130:18 103:12,18 149:12,14,18 149:20,25 150:5,10,13 167:13 190:20 191:14 193:16 197:10 223:15 224:1 <b>standardized</b> 100:22	<b>standards</b> 95:20 95:25 96:2,6 96:18 100:23 101:2 <b>standing</b> 106:12 <b>standpoint</b> 141:9 213:8,9 237:23 <b>start</b> 8:15,18 10:20,20 42:16 63:16,19 64:7 108:25 110:12 115:3 238:24 238:25 248:7 <b>started</b> 7:16 28:19 38:11 60:4 226:10 <b>starting</b> 29:1 141:1 <b>state</b> 3:10 7:9 24:3 69:5 95:22 133:19 135:16 140:11 <b>stated</b> 138:11 140:8 155:4 167:12 223:12 227:3 229:1 241:1 <b>statement</b> 46:15 150:17,22,24 151:14,19 152:2,5,6,7,8 153:13,20 154:9,18,24 166:10 234:14 <b>statements</b> 65:17 151:7 213:17 <b>states</b> 1:1 3:7 167:23 190:19 <b>statesim</b> 23:24 <b>statistical</b> 238:5
---	---	--	---	--

Michael P. Woods, M.D.

Page 292

<b>stay</b> 108:3	108:24	149:14,22	172:12,22	140:9,14,16,19
<b>stayed</b> 104:8	<b>stretching</b> 212:2	150:2 152:19	173:18,18	141:9 204:6,10
227:9	213:1	160:18,19,24	174:17 177:17	207:14 211:24
<b>step</b> 242:9,9	<b>stretchy</b> 180:16	161:24 162:4,9	178:16 185:7,9	<b>sufu</b> 150:18
<b>stephen</b> 242:1	181:12 182:16	162:12,13	185:10,12,12	168:2 184:21
<b>stevens</b> 2:8	183:18	163:11,13,19	185:15,19	191:19
<b>stiff</b> 227:24	<b>strictly</b> 188:23	164:6,21 165:3	186:3 195:17	<b>suggest</b> 27:11
228:18	<b>strike</b> 14:24	165:4,17	201:18 210:11	34:19 35:7
<b>stipulations</b>	43:11,23 67:9	170:24 172:3,4	220:23 223:7	109:17 149:14
256:13	78:8 80:13	173:22 178:23	223:21 227:18	<b>suggested</b> 177:7
<b>stop</b> 16:16 64:10	89:4 102:25	187:13 188:2	228:4 236:24	177:15 178:8
<b>storage</b> 121:18	108:17 110:19	189:19,20	237:2,22	178:10
<b>straining</b> 224:15	131:5 139:21	192:15,16	239:12,16	<b>suggesting</b> 173:9
<b>stream</b> 224:13	156:21 175:19	195:5,15,16,19	240:1,16,18,22	189:10
<b>strength</b> 245:21	182:21 188:8	195:23 201:6	240:25	<b>suggestions</b>
<b>stress</b> 5:24 6:5	201:24 215:4	202:24 203:6	<b>stuff</b> 56:10	177:12
6:10 8:25 28:8	220:6 240:23	203:18,22	58:19 117:4	<b>suggests</b> 34:23
35:16 79:18	<b>strip</b> 166:21	205:4 214:21	<b>subject</b> 44:2	114:11 173:14
151:15 167:14	<b>strong</b> 92:8	215:6,7 222:7	<b>subjective</b>	<b>sui</b> 63:6 85:10
188:24 189:6	245:14	222:11 228:23	201:21 202:1	98:19 127:1
190:6,13,16	<b>strongest</b> 156:13	228:24 229:6	207:18 223:11	135:12 155:6
191:5,10,15	156:20 157:9	233:23 236:13	224:11,12	167:1 180:10
192:20 193:8	<b>strongly</b> 142:12	236:14 240:21	238:6,10	180:12 185:20
193:17 194:16	215:19	248:15 250:22	<b>submicronic</b>	186:2 190:20
194:25 195:9	<b>structure</b> 194:7	254:5,7	193:21	223:16
195:21,24	<b>studied</b> 19:4	<b>study</b> 28:17	<b>submission</b> 43:9	<b>suit</b> 79:11
196:12,23	157:14 195:17	33:15 34:23	182:17,20	256:19
197:25 198:5	232:4	46:22 47:9,9	<b>submissions</b>	<b>suite</b> 3:11 4:5,11
199:9 200:7,23	<b>studies</b> 19:5	47:12,14,15,16	182:9	4:15
201:15 202:4	27:19 28:23,24	47:23 62:14	<b>submit</b> 53:24	<b>suited</b> 167:24
202:25 203:15	28:25 29:3	63:1 74:6 97:1	182:3,6	<b>sum</b> 134:7
203:19 204:16	34:25 35:3,5	97:2,6 101:2	<b>submitted</b> 53:6	<b>summarize</b>
205:5 206:3,11	43:1 45:5	105:1,5,6,13	182:22	205:11
206:16,24	49:11 59:7	105:18,20	<b>subscribed</b>	<b>summation</b>
207:15 209:6	62:9 68:22	106:4,14,17	259:14	119:7,9
210:1,14	84:10,16,18,21	107:5,8,13,14	<b>subsequently</b>	<b>summations</b>
211:17 212:5	109:21,24,24	108:1,4 110:4	242:2	121:17 249:22
213:3,13,16	110:12,16,19	110:9,22 111:8	<b>substance</b> 259:5	<b>summits</b> 24:9
216:25 218:21	111:12,21,25	111:20 112:14	<b>suburethral</b> 6:9	25:1,19
219:23 221:17	112:3,5,15	112:16,21	8:13 31:20	<b>sun</b> 176:16
222:14 224:23	113:1,8,9,15	113:3,5,8,10	99:11 144:13	<b>supplied</b> 172:8
228:25 229:9	113:18,19,20	113:13 133:14	172:10 190:21	<b>support</b> 27:12
229:18 232:2,8	113:22 133:9	134:8,8 152:22	197:3 216:12	27:17 69:16
233:19 235:1	133:12,12,17	153:4,6 160:3	<b>suburethrally</b>	114:13 180:10
235:14 241:3	133:18 140:12	164:17,23	31:20	203:7 251:6
<b>stretch</b> 101:17	141:16,17,18	165:14,19,24	<b>success</b> 21:19	252:4,16

Michael P. Woods, M.D.

Page 293

253:10	29:24 34:10	<b>systematic</b> 193:5	229:23 230:1	131:23
<b>supported</b> 168:2	36:18,25 37:10	195:8 197:20	236:12 240:21	<b>tell</b> 8:9 11:20,23
172:3	82:20 86:5	197:21 198:11	248:6,11,25	11:24 20:7
<b>supporter</b>	139:13 162:20	198:14	250:6	21:3,17 23:10
134:17	162:22 172:10	<b>systemic</b> 35:1	<b>talked</b> 34:1 53:1	39:10,14 42:2
<b>supposed</b>	190:20 223:13	70:1,14 74:7	62:10 80:17	49:18,20 52:10
188:14 250:3	232:2 238:2	164:2 165:5	99:10 109:8,10	61:15 89:4
<b>supraphysiolo...</b>	251:2,14,23	173:5,22	109:20 149:7	98:8 111:14
107:1	253:8	189:19	149:21 155:1	123:1,22 126:9
<b>sure</b> 9:4 24:2,24	<b>surgical</b> 8:24		161:24 167:8	133:4,17
25:22 37:19	13:6 131:25	<b>T</b>	168:21 172:23	137:24 138:10
41:25 48:4	155:5 204:25	<b>t</b> 166:23 258:1	179:25 182:13	138:25 165:20
51:11 57:8	223:16 228:13	<b>ta</b> 91:1	<b>talking</b> 16:2,5	165:24 169:13
63:4 65:25	245:13	<b>tabbed</b> 192:4	20:2,7 29:7	169:13 170:4
82:5 95:19	<b>surprise</b> 134:19	<b>table</b> 48:20	36:1 104:1,14	170:18 202:2
100:2,4 108:21	134:20,21,23	126:24 162:18	208:12 215:24	206:14 224:21
108:22 119:6,7	135:19	197:24 199:15	236:13,14	238:11 244:24
122:18 123:20	<b>surprised</b> 40:23	199:16 224:4,5	249:21,22	247:2 248:20
127:11 131:11	41:10 134:25	<b>taiwan</b> 87:10,24	<b>talks</b> 227:19	250:11,14,20
141:6 144:16	<b>survey</b> 150:11	88:6,8,23,24	<b>tamussino</b>	251:1,4,7,11
147:19 150:25	<b>suspect</b> 37:1	89:6 172:9,22	174:23	251:17,23
155:17 161:9	99:1	173:18	<b>tape</b> 6:5,7	252:2,9,14
176:10 204:5	<b>suspensions</b>	<b>take</b> 25:9 48:2,2	190:21,22	253:5,9 254:4
216:9 226:9	161:11	66:1,2,4,5,17	194:1 217:15	255:1 256:7
<b>surgeon</b> 27:8	<b>suture</b> 138:17	82:21 85:3	227:25 228:13	<b>telling</b> 166:22
29:19 46:13	138:23	101:24 111:2	228:18,21	<b>tells</b> 224:25
196:4,5 234:5	<b>sutures</b> 186:7,10	112:4,14 138:1	239:3,12,17,18	<b>ten</b> 64:23 70:21
234:9 242:19	207:9,10	139:7 151:1	239:20,22	136:19 144:12
243:11	<b>svenningsen</b>	154:9 168:15	240:7 244:10	145:6,9 183:25
<b>surgeons</b> 22:24	223:3,4,14	174:9,10 179:5	<b>tapes</b> 194:13	197:11 201:19
29:7 86:2	<b>sweden</b> 28:24	192:4 218:6	<b>tasked</b> 187:16	202:7 217:9
102:13 129:19	<b>swedish</b> 29:4	227:17 242:9	233:25	221:8 224:9
130:3 138:13	30:3	<b>taken</b> 3:6,8	<b>taught</b> 90:20	<b>tender</b> 141:5
138:20 209:9	<b>swing</b> 168:11	42:24 48:7	209:8	<b>tenderness</b>
209:19 214:20	<b>switched</b> 81:14	61:1 81:1	197:18	197:18
229:21,23	<b>sworn</b> 7:5 256:7	102:2 137:8	<b>tends</b> 114:16	
230:1,4,24	259:14	174:12 225:10	227:24 228:17	
231:4 234:11	<b>symptoms</b> 92:1	256:12,15	<b>tenplus</b> 184:3	
234:14 237:19	239:24	<b>talk</b> 13:13 14:7,9	<b>tension</b> 106:25	
242:7,9 244:21	<b>synthetic</b> 10:13	15:17 16:4	155:10,23	
244:25	10:16,16,21	25:2,19 27:5	156:2,5,14	
<b>surgeries</b> 139:8	141:21 142:3	37:8 102:17	<b>techniques</b>	157:1 158:24
144:22 145:3	200:14 228:16	103:10 104:5	35:24 168:25	158:25 159:8
246:18,23	232:4	130:4,7 156:22	<b>technologies</b>	159:13 234:6
<b>surgery</b> 5:24	<b>system</b> 1:3 96:15	184:5,20 204:9	1:24 130:9	<b>tensioned</b>
12:2 22:23	162:21 173:24	222:4 223:25	158:13 159:24	

Michael P. Woods, M.D.

Page 294

<b>tensionfree</b> 6:5 6:7 156:8,10 190:21	24:15 27:1 31:6 34:11 38:9,10 40:9	69:21 77:23 101:14 109:1 131:11,11,13	248:15 <b>think</b> 8:20,21 15:24 24:10	52:13,23 93:1 136:24 153:6 173:3 179:10
<b>tensioning</b> 158:22 159:15	42:23 45:23 49:8,20 54:6	131:13 151:18 153:9 156:11	27:22 28:18 32:11 46:12	179:15,18,22 222:21
<b>tenyear</b> 201:21 201:25 215:4 217:16 223:6,8 223:21 246:23	56:5 65:9 66:25 72:25 75:12 81:23 96:12 97:21	157:17 158:12 158:17 169:9 172:1 173:14 177:2 197:17	54:24 58:5 82:3 89:8,8 96:19 105:14 105:15,24	<b>threeyear</b> 179:13 <b>thumb</b> 26:11,22 49:9 61:8,10 61:12 75:2,6 75:10,12,23 116:16
<b>term</b> 47:12 140:23 149:20 195:25 196:1 203:24 215:23	99:16 105:25 109:25 110:1 113:7 115:18 117:15,20	251:5,10,17,24 252:1,15 118:7 124:14 124:17 125:12	106:2 109:6,9 114:5 119:16 129:24 130:18 133:8 144:23	<b>tier</b> 172:17 <b>ties</b> 133:6 <b>tighter</b> 160:7 <b>time</b> 12:2,21
<b>terms</b> 215:8	118:4 120:5	126:22 129:5	144:24 145:19	13:20,25 14:8 14:16 17:12 22:13 32:3
<b>terrible</b> 30:6 186:15,17	124:17 126:11 128:2,7 134:9	130:1,9 135:11	149:17 150:18 154:24 159:15	36:19 39:10
<b>test</b> 82:21 106:11 107:11 158:16 181:2	134:10 135:21 136:13,19 142:25 147:22	<b>thermchoice</b> 61:11 62:15 72:11 101:3	164:9 165:18 166:25 170:9 176:24 179:12	43:15 50:17,20 51:17 53:2,18 54:3,8 55:8,9
<b>testified</b> 7:6 55:15,16 186:18 187:13 189:25 190:4 202:17 218:5 222:10 235:2	147:22 148:6 148:19,21 151:2,23 154:15,16 157:7,8 163:15 163:23 166:22	119:2,3 141:6 141:20 142:13 155:17 166:23 243:22,22 251:14 253:8 255:9	183:25 186:18 211:25 214:23 216:22 219:17 222:9 226:1	55:10 57:7 58:11,12 59:10
<b>testify</b> 21:3	167:18 170:17	<b>theyre</b> 26:8 177:23,23	242:4,23 244:9 248:8 249:10	59:16 60:6
<b>testimony</b> 5:4 14:6 15:13 17:20 57:20 67:21 68:5 71:23 118:4 136:11 137:12 181:2 202:20 253:1 256:20	172:25,25 173:4 175:21 176:4,18 180:5 181:13,19 184:2 185:18 192:22,25 204:8,23 208:2 212:7,9 215:25	<b>thing</b> 39:10 75:9 76:6 105:20 130:22	251:16,17 252:25 254:25 255:9	63:4 66:4,22 76:13 78:1,20 91:22 92:6,9 103:10 114:16
<b>testing</b> 100:21 100:22,22 101:5 212:2,6 212:7,19,20,25	218:8 234:11 237:21,21 247:17 249:18 251:16 254:9	<b>things</b> 25:15 30:9 32:4 51:4 51:7 57:14	<b>thinking</b> 230:21 257:13	124:5,6,15,24 125:6 137:15 137:17 139:23 140:13 143:9
<b>texas</b> 126:15	<b>theirs</b> 72:1	72:3 74:7 93:3	<b>thisi</b> 23:25	156:23 167:16
<b>textbooks</b> 51:2	<b>theory</b> 99:8	96:12 97:22	<b>thomas</b> 76:22	170:1,10
<b>thank</b> 40:16 102:23 121:2 137:18 246:13	180:11 202:11 <b>thereof</b> 230:5 <b>theres</b> 13:7	102:12 109:24 126:10 130:24 148:14 165:7 184:21 187:9 191:24 205:1 208:19 224:8	<b>thorough</b> 113:8 <b>thought</b> 25:3 55:14 84:23 89:5 151:5,9 151:12 172:11 119:16	171:10 179:13 179:18 180:20 203:25 204:2 220:21 226:4 226:10,16,17 226:19 227:2 243:12 246:23 256:12
<b>thanks</b> 138:24	20:23 24:24	236:9 238:25	<b>three</b> 34:9 38:3	243:12 246:23 256:12
<b>thats</b> 12:6 15:23 18:12 20:11	27:22,24 50:1	241:14 242:15 245:3 248:14	38:7 48:1 51:10,10,12,20	<b>timed</b> 35:23 <b>times</b> 42:4 51:8

Michael P. Woods, M.D.

Page 295

51:10,11,12,20	252:18 254:25	257:14,16	229:18 233:19	232:9
52:13 103:24	255:9	<b>transcription</b>	241:3 243:21	<b>trouble</b> 52:19
124:8,12	<b>tomblin</b> 2:17	259:4	<b>treated</b> 143:8	<b>true</b> 171:21
130:11 135:14	<b>top</b> 13:17 42:12	<b>transferred</b>	<b>treating</b> 188:5	190:24 256:14
136:2,22,24,25	43:16 203:17	81:12	191:4,15	<b>truth</b> 256:7,8,8
137:2 221:4,8	<b>topa</b> 180:1,3,4	<b>transfusion</b> 9:15	192:20 194:24	<b>truthfully</b> 52:8
227:5	180:14,17,22	<b>transfusionand</b>	195:21 221:25	136:12
<b>timewhere</b>	181:3,10 182:4	9:23	232:8 235:13	<b>try</b> 24:15 56:9
102:8	182:12,14,18	<b>transfusioninf...</b>	243:19,24	68:25 70:5
<b>tissue</b> 10:10 11:1	182:25 183:7	9:25	244:10	125:2 143:18
11:25 12:24	184:6,7,10,19	<b>transobturator</b>	<b>treatment</b> 6:5,9	243:12
40:24 46:7,10	<b>topics</b> 187:10	6:9 190:22	28:8 35:16	<b>trying</b> 32:4 39:7
106:20 139:10	<b>toplevel</b> 74:18	<b>transvaginally</b>	51:3,6,11	
141:4 168:15	<b>toss</b> 53:24	142:3	53:25 54:2	
168:18 175:22	<b>tossed</b> 57:1	<b>transverse</b>	59:7 66:9 71:1	
186:6 194:4,11	<b>total</b> 17:16	186:2 188:23	89:7 96:13,19	
236:10 239:2	33:17 144:20	190:13 195:24	100:17 167:14	
244:6 245:7,10	145:4 184:1	<b>traumatized</b>	202:24 203:19	
<b>tissues</b> 41:11	237:25 246:10	228:20	205:5 206:24	181:20 245:16
102:17 104:13	<b>totally</b> 15:11	<b>travel</b> 88:3,5,22	223:16 224:23	252:19
138:18,23	<b>town</b> 139:6	123:23 124:2,4	228:25 231:25	<b>tubal</b> 207:7
169:21 244:5	<b>track</b> 16:14,15	125:17,21	234:25 238:6	<b>tube</b> 138:14,16
245:8	16:16,20 20:18	129:13 131:15	238:10 243:24	138:21
<b>today</b> 15:17,21	21:7,18 23:19	212:17 226:3	<b>tremendous</b>	<b>turn</b> 24:4 37:22
16:2 18:19	36:14 47:18,20	226:10,17	86:3 95:24	176:3 193:14
20:16 30:17	47:24 118:8	<b>traveled</b> 226:11	207:11	203:11 224:3
32:5,11,20	146:2,23,25	<b>traveling</b> 60:21	<b>trial</b> 6:11 55:10	227:18 237:9
38:20 40:12	161:18,24	123:21	55:15,16	238:16
50:12,23 54:17	162:9,11 174:7	<b>treat</b> 142:15,18	111:15 117:6	<b>tv</b> 175:18
75:22 77:7	218:23 220:15	142:22 143:6	164:14 173:3	<b>tvt</b> 7:18 8:10,13
93:23 111:7	<b>tracked</b> 21:23	190:16 191:10	176:22 191:8	10:21 11:10,10
121:14 133:5	160:20,24	193:8,16	222:15 236:21	11:17 12:10,13
164:7 170:7	162:5 163:13	194:16 195:9	237:17 240:4	13:2,20,25
173:7 208:12	174:19	196:12,23	<b>trials</b> 62:8	14:8,16 15:9
216:20 217:2	<b>tracks</b> 111:15	198:5 199:9	151:21 180:9	16:4,9,18,20
222:9 249:3	<b>tract</b> 9:19,25	200:6,23	190:25 205:4	17:6,10,16,17
252:24	<b>trade</b> 249:25	201:15 202:4	<b>tried</b> 70:3 81:9	17:21 18:1,10
<b>toglia</b> 50:16	<b>trained</b> 85:24	203:15 204:16	209:19,25	18:21 19:6,11
<b>told</b> 20:23 39:3	142:11,13	206:3,11,16	210:6	19:14 20:2,5,8
39:18 40:7	<b>training</b> 42:19	207:15 209:6	<b>trip</b> 87:19,22	20:15,19 22:16
132:9,11,15,18	84:9,17 127:9	209:18 210:1	88:1,7,8,23	24:9 25:1 28:9
145:19 156:25	127:17 131:25	210:14 211:16	89:15,17	28:9 29:25
165:18 189:1	132:3 142:9	211:19 212:5	<b>trips</b> 87:13	30:22 34:19,20
204:2 206:9	218:17 245:13	213:3 216:24	124:3 184:3,4	34:23 35:17,17
216:22 242:23	<b>trajectory</b> 197:4	217:3 219:22	<b>trocar</b> 212:17,23	35:25 36:5
249:9 250:10	<b>transcript</b>	220:10 221:17	248:13	38:12,21 39:12
		222:14 229:9	<b>trocars</b> 155:13	39:24 40:7,13

Michael P. Woods, M.D.

Page 296

40:17,18,22	193:7 194:16	244:20 245:18	210:2,2 220:9	<b>unfortunately</b>
41:1,5,14,15	194:16,24	245:23 246:5	244:15,22	124:7
41:18,20,21,22	195:5,9,10,14	246:11 247:21	245:1,5	<b>unique</b> 7:20
43:13 46:22	195:16,20,23	248:4,8 250:21	<b>typed</b> 69:6	<b>unit</b> 93:5
47:4,7 62:10	196:22 197:14	251:7,15,24	<b>types</b> 10:18	<b>united</b> 1:1 3:7
62:14 68:17	198:3,17 200:6	252:6 253:22	139:11 148:4	23:24
85:13 91:25	200:16,23	254:1,19	206:10,15	<b>units</b> 93:3
97:19 99:5,13	201:6,14,19	<b>tvto</b> 17:18 28:9	210:22 231:9	<b>universe</b> 145:25
101:6,12	202:4,24 203:7	35:18 104:2,4	<b>U</b>	<b>university</b> 23:2
102:13,14,14	203:14,16,18	127:25 238:4,7	<b>u</b> 1:6 29:8 79:14	81:12,13 89:12
104:2,3,4	204:1,15 205:5	239:13,17	101:3 104:3	<b>unmet</b> 156:13
106:17,18,19	205:9 206:2,23	<b>tvts</b> 41:13,19	<b>udi</b> 47:11	156:20 157:9
107:4 108:3,7	207:15,22,23	104:2 188:22	<b>uhhuh</b> 85:17	157:11
108:9,11,17,18	208:7,12,16,22	218:3,8,10	<b>unprolapsed</b>	
112:10,18,22	209:3,16,18	<b>twice</b> 39:3 51:10	9:13	<b>unreliable</b>
113:4,11,22	210:1,14,18,22	231:16 239:22	219:13	
114:1,6,7,12	211:2,4,22	<b>two</b> 25:3 51:10	<b>unsuccessful</b>	
127:21 128:19	212:5,12 213:2	52:13,23 53:14	180:15	
128:22 129:8	213:9,20 214:3	57:13 59:4,5	<b>unsure</b> 37:22	
130:19 140:14	214:8 215:2,6	59:23 83:17	64:9 76:13	
141:10 142:19	215:10 216:2	87:12 89:1	88:18,21	
142:22 143:6,9	216:21,24	119:16 124:13	119:15 136:4	
143:22 144:13	217:3,8,9,22	124:24 125:2,6	<b>update</b> 9:1	
144:14,17	218:2,11,12,18	125:9 142:24	116:21	
145:10 149:11	218:24 219:14	145:8 154:16	<b>updated</b> 75:14	
149:15,15	219:22 220:2	166:24 174:15	<b>updating</b> 117:4	
150:4,7,21	221:2,16	174:20 178:24	<b>upper</b> 141:14	
153:4 154:2,13	222:11,15	179:2 186:24	205:16	
154:14,20,23	223:1,5,8,21	190:25 210:8	<b>upyou</b> 253:25	
155:10,12,23	224:22 227:1	226:11,13	<b>ureterolysis</b>	
156:7,14,22	227:20 228:12	227:11 239:12	145:18	
157:9,13,18	228:14,25	239:16	<b>ureters</b> 12:3	
158:13 159:8	229:3,13,18,24	<b>twoyear</b> 232:1	<b>urethra</b> 12:5	
162:23 163:3	230:2,6,9,12	<b>tyler</b> 2:19	155:15 156:11	
164:15,20,25	230:16 231:12	<b>type</b> 8:17 10:5	16:7 71:4	
165:19 166:3	231:19 232:7	17:23 18:11	156:12 159:5	
166:13,21	233:19 234:1,1	30:12 42:14	159:25 186:11	
167:12 169:24	234:3,25	55:17 69:2	197:4	
170:8,20 171:8	235:13 236:13	91:16 98:18	<b>urethral</b> 10:1	
178:21 179:7	236:16,21	139:8 142:21	146:16,16,17	
180:11 184:15	237:5,22 238:3	145:4 148:1	217:17	
187:18,22,24	238:7,12,22	167:23 168:1	<b>urgency</b> 239:24	
188:4,18 189:1	239:13,21	184:17,23	<b>urinary</b> 5:24	
189:5,11 190:5	240:7,12,19,23	191:3,6,9,11	6:10 8:25 9:19	
190:5,16 191:4	241:2 242:6,11	191:14,20	9:25 12:17	
191:6,9 192:19	243:3,19	193:22 208:11	28:8 35:16	

Michael P. Woods, M.D.

Page 297

79:19 114:16	111:12 128:15	1:12,13,14,15	77:24 79:7	151:16 161:7
142:24 188:24	141:21 142:2	1:16,17,18,19	255:6	168:13 170:6
189:6,7 190:6	155:23 159:18	1:20 2:2,3,4,5	<b>vesicovaginal</b>	170:18 176:7
190:14,16	169:13 185:20	2:6,7,8,9,10,11	79:22	176:10 197:20
191:10,15	186:1,7,9,9	2:12,13,14,15	<b>vessels</b> 12:3	201:9 216:9
192:20 193:8	188:19,22	2:16,17,18,19	194:9 245:6,9	228:23 249:23
193:17 194:17	189:4 190:5,16	2:20,21,22,23	<b>vesselsealing</b>	249:25
194:25 195:21	191:4,15	2:24 7:14	63:4	<b>wanted</b> 62:1
195:24 196:12	192:20 194:23	78:14,24 79:1	<b>vice</b> 92:22	66:12 84:9,20
197:25 198:5	196:15,18	79:3,5	<b>vicryl</b> 186:4	92:4,5,6
200:7 201:15	203:15 206:11	<b>vagina</b> 12:4	206:19	137:25 152:12
202:25 203:15	206:18 209:5	142:23 162:24	<b>viewed</b> 174:13	169:21 189:17
204:16 205:5	210:1 212:5	<b>vaginal</b> 6:5,7	<b>viewpoint</b> 74:18	204:5 221:23
206:11,24	213:2,7,13	10:2 11:9	<b>virginia</b> 1:1	248:12,15
207:16 213:16	216:17 228:20	94:22 97:5	<b>visible</b> 239:19	<b>wants</b> 192:5
222:14 224:23	232:8 233:19	139:10,12	<b>visited</b> 136:2,22	<b>ward</b> 162:15
228:25 229:9	241:3 242:7,10	141:24 146:16	136:25	163:8 248:25
231:25 232:2	<b>useful</b> 195:20	197:13 217:17	<b>visits</b> 197:2	<b>warnings</b> 12:6
235:14	<b>usefulness</b>	224:17 228:19	<b>vivo</b> 104:5,15	92:19 93:1,7
<b>urine</b> 158:18	195:13 237:23	244:4	<b>void</b> 224:15	93:12 94:6,9
<b>uro</b> 118:7	<b>user</b> 135:15	<b>vague</b> 97:9,13	<b>voiding</b> 12:19	100:12
<b>urodynamic</b> 6:5	196:16,20	98:4 101:7	13:16 35:23	<b>warranted</b> 46:8
201:22 202:1	209:12 247:21	<b>valid</b> 180:23	146:15 161:12	<b>washington</b> 4:12
<b>urogyn</b> 87:9,10	<b>uses</b> 38:12	221:15	161:17 197:9	<b>wasnt</b> 29:8 32:6
<b>urogynecologist</b>	<b>usually</b> 97:16	<b>validated</b> 140:25	224:7,10,11,12	108:12 148:23
82:14,16 139:3	141:3 145:12	<b>validity</b> 133:14	146:21	152:7 158:6
<b>urogynecology</b>	179:14	<b>valley</b> 96:23	<b>volume</b> 135:15	166:12,20
82:9 139:5	<b>utility</b> 192:19	<b>valleylab</b> 94:24	228:9	170:3 180:19
<b>urological</b>	195:14 196:3	96:8,24	<b>vs</b> 6:9	180:21 185:14
195:18	201:19 203:10	<b>valleylabs</b> 96:23	<hr/>	188:6 226:19
<b>urologist</b> 143:12	209:5 214:8	<b>valpas</b> 248:25	<b>way</b> 8:23 19:19	
149:8	215:10 234:24	<b>vanbuskir</b> 1:20	31:18 36:14	
<b>urology</b> 58:1	237:7,23	<b>variability</b>	69:21 84:24	
161:3 191:18	245:23	215:22	93:11 99:12	
217:13	<b>utilize</b> 138:14,21	<b>variable</b> 141:14	<b>waited</b> 142:8	101:2 135:17
<b>usage</b> 155:7	210:9 215:7	<b>variance</b> 130:23	<b>walk</b> 251:22	155:10 205:15
218:2	<b>utilized</b> 19:4	<b>varies</b> 36:6	<b>want</b> 7:16,23 9:5	211:15,18
<b>use</b> 22:15,23	106:18 110:10	<b>various</b> 8:22	13:10 20:11	253:18
24:12 27:15	194:16 196:12	68:22 99:10	24:12,20 26:19	<b>ways</b> 30:14
29:14,15 30:16	206:16 207:4	135:14 139:11	45:19 65:22	109:1
31:19 32:21	230:9	194:1 197:25	66:6 70:15	<b>wcllp</b> 4:7,7
33:1 35:20,21	<b>utilizing</b> 218:19	230:5	81:23 84:15	<b>weaves</b> 194:1
36:2,4,9,15,25	<b>uttered</b> 40:21	<b>vary</b> 158:25	100:23 112:15	<b>webb</b> 1:12
42:21 45:11,16	<hr/>	<b>vast</b> 226:19	136:16,16	<b>website</b> 152:16
65:11 91:4	<hr/>	<b>vegas</b> 123:11	137:11 139:19	153:17
96:6 108:16	<b>v</b> 1:7,8,9,10,11	<b>versus</b> 10:16	140:22 144:16	<b>weed</b> 70:3

Michael P. Woods, M.D.

Page 298

<b>week</b> 38:1,2 124:13,25 125:3,6 139:1 139:1 249:25	<b>withdraw</b> 221:5 235:10 <b>witness</b> 7:13 13:6 18:17,23	198:22 202:7 202:13 203:3 204:19 205:21 206:5 207:2,25	83:23 85:7,10 85:13,15 93:7 97:17 98:13 130:12 132:10	190:10 <b>written</b> 85:19 87:2 89:9 90:5 133:2 147:4 177:22
<b>weekends</b> 125:3	19:3 20:12,25	209:8 211:8	132:12 168:25	<b>wrong</b> 252:15
<b>weeks</b> 54:11 125:8 141:4 186:24	21:11,17 23:13 25:7 26:13 28:4 33:8	213:5,22 214:10 215:13 218:14 219:2	206:6,20 216:10 227:4 242:3	<b>X</b>
<b>weight</b> 42:10 180:13 184:18 184:20 185:3	39:20 40:2 41:8 42:3 44:15 48:5	219:17 221:9 224:25 225:6 229:5,15 233:1	234:19 235:17 235:23 240:14 242:14 246:1	<b>Y</b>
<b>welldone</b> 240:16	49:22 51:19,24	249:19 252:6	94:9,17,21 97:18 108:4 124:11,19,21	<b>yeah</b> 26:21,24 40:6 48:23 50:16 61:14 67:7,8 101:24 120:1 148:5 185:18 208:2
<b>went</b> 42:19 58:11,21 80:1 84:7 87:15 96:20 103:5,8 121:11 124:18 246:17 247:6 248:17	52:2,5,13,21 55:20 56:18 61:17 64:17 75:19 78:3 83:12 86:9,17 90:17 93:19 94:17 98:3,12	249:19 252:6 257:1	181:3 184:6,7 209:12 247:20 255:2	<b>year</b> 17:11 29:10 58:7 63:23 64:11,18 82:22 90:25 92:13 120:7 124:16 125:7 145:7 146:21,22,24 150:23 151:22 153:18,24 219:12 225:23 226:9,18 238:2 239:18
<b>west</b> 1:1	101:9 103:8	<b>woman</b> 34:9 196:18 213:13 239:18,21	197:15 202:8 199:9	<b>working</b> 63:16 96:9 118:6 124:9,17 197:8
<b>weve</b> 119:19 149:21	104:21 106:24 110:8 111:1	<b>womans</b> 197:15 199:9	250:4	120:7 124:16 125:7 145:7 146:21,22,24 150:23 151:22 153:18,24 219:12 225:23 226:9,18 238:2 239:18
<b>whats</b> 18:6,9 27:1 48:11 50:13 55:10 98:25 99:25 105:1 115:11 116:2 120:20 122:20 140:14 155:10 206:14 217:20 238:20 247:2,25	114:1 116:24 117:2 120:24 122:2,14 126:8 126:12 127:7 128:4 129:24 135:3 136:18 146:5 148:3 151:9 153:16 153:23 156:17 157:21 158:15 159:3,11 160:2 160:9,15 164:2 165:3,23 166:6	<b>women</b> 5:24 188:4,24 189:12 191:5 191:10 193:17 196:12 197:13 200:9 201:16 202:5 203:20 204:15 205:6 206:2 219:23 221:25 237:12 238:1 239:2,12 239:16 245:17	<b>world</b> 84:11 86:2 184:4 229:1	<b>yearly</b> 218:25 <b>years</b> 19:5 48:1 56:21 64:23 76:9 81:19 92:13 110:13 110:13 118:3,6 118:15,19,24 119:1,3,5 121:18 124:16 135:15 136:8
<b>whatsoever</b> 219:21 255:6	167:22 168:9 168:24 169:18 170:14 171:10 171:15 173:13 174:13 177:6 178:10 181:6 183:14 186:9 187:16 189:16 190:19 191:17 193:11 194:19 196:15 197:1	<b>womens</b> 57:25 204:24	<b>wont</b> 251:13 <b>woods</b> 1:23 3:5 5:14 7:4,10,11 52:7 78:14,24 79:1,3,5,8 256:6 259:8	<b>wouldnt</b> 97:23 118:14 122:2 123:22 125:8 134:21 144:12 160:10
<b>whereof</b> 256:20		<b>word</b> 81:24	<b>wound</b> 9:20 10:3 198:16 199:12 199:12,14,17	<b>wounds</b> 197:3 139:17 140:1 144:12 145:9 152:20,24 153:1,2,7,9
<b>whisner</b> 2:16		109:9 128:8	66:17 219:11	162:19 163:1,4 163:5 170:15 173:3 178:24
<b>whos</b> 37:12 76:14		<b>words</b> 40:21	<b>writing</b> 8:4 66:21,25 256:9	179:2,10,15,18
<b>wide</b> 157:13 211:12		<b>work</b> 31:24	<b>writings</b> 190:1	
<b>widely</b> 194:13		54:20 70:16		
<b>width</b> 157:16				
<b>willing</b> 24:14				
<b>wine</b> 123:19 173:18				
<b>wish</b> 61:1				

Michael P. Woods, M.D.

Page 299

179:22 197:11	93:25 94:3,6	12:4,5 34:25	<b>12cv02952</b> 1:7	<b>14cv29624</b> 2:24
201:19 202:7	113:8,9,16,21	48:8,12 58:2	<b>12cv07924</b> 1:8	<b>15</b> 5:20 6:7 55:1
204:7,9,9,9	120:7 121:14	101:14 137:7	<b>12cv09765</b> 1:9	57:5 136:7
207:5 215:21	123:1,23	138:14,16,21	<b>12md02327</b> 1:3	139:5 223:17
216:4 217:9,23	125:14 126:25	148:18 172:25	<b>12month</b> 222:25	223:20
222:21 224:9	127:21 131:24	190:25,25	<b>13</b> 6:4 17:11	<b>15minute</b> 54:5
226:21 237:13	132:3,6 133:18	195:12 199:1,1	163:3 199:19	<b>16</b> 5:16 6:9 24:3
238:14 239:8	134:10 144:21	199:2 200:14	199:22 204:9	24:5 161:12,17
247:4,15 249:9	147:7,9 157:24	201:23 211:12	<b>135</b> 121:25	227:14,18
249:13 250:23	173:7,8 175:21	223:11 225:18	<b>13cv02565</b> 1:10	<b>164</b> 102:10
252:1	177:19 178:7	233:21 244:2	<b>13cv02919</b> 1:11	104:7,21
<b>yesterday</b> 51:17	179:18 189:1	<b>10</b> 5:20,21,22	<b>13cv04517</b> 1:12	<b>167</b> 101:21
53:9 65:19	193:5 201:12	20:8 48:6,6	<b>13cv04730</b> 1:13	<b>17</b> 6:11 122:19
<b>yetthen</b> 146:17	208:12 218:8	191:21 193:15	<b>13cv07283</b> 1:14	152:19,24
<b>youd</b> 10:17	222:10 223:20	200:13 215:5	<b>13cv10150</b> 1:15	153:1,2,9
32:20 73:21	228:4 233:14	<b>100</b> 40:15 50:22	<b>13cv11022</b> 1:16	154:11 204:7,9
120:3 237:9	235:2 236:24	50:25 53:5,5,6	<b>13cv14355</b> 1:17	215:21 236:17
247:20	244:9 246:18	54:13,24 66:19	<b>13cv14718</b> 1:18	250:23 251:11
<b>youre</b> 15:2,12,17	246:19 247:3	120:4 140:4	<b>13cv14799</b> 1:19	251:17,24
16:1 27:22	247:14 249:7,8	144:12,21	<b>13cv16183</b> 1:20	252:1 253:9
36:8 52:7	<b>Z</b>	<b>102</b> 5:15	<b>13cv16564</b> 2:2	<b>17year</b> 215:6
66:12 67:4		<b>1020</b> 4:15	<b>13cv17012</b> 2:3	250:12 251:6
83:21 90:11		<b>10250</b> 3:10	<b>13cv18479</b> 2:4	251:10 252:3
91:6 92:15,19	<b>0</b>	<b>105</b> 3:11	<b>13cv22606</b> 2:5	252:16,22
93:12 94:12,14	<b>0</b> 198:23 200:15	<b>1099s</b> 249:22	<b>13cv24393</b> 2:6	253:21
96:16 98:1	224:18	<b>10plus</b> 204:9	<b>13cv29260</b> 2:7	<b>18</b> 228:9
100:3 122:22	<b>000</b> 16:12 17:16	<b>10year</b> 215:21	<b>13cv29918</b> 2:8	<b>187</b> 5:8
126:9,10 128:2	17:21 33:15	<b>11</b> 5:21,23 12:24	<b>13cv31818</b> 2:9	<b>19</b> 122:18
135:7 136:10	55:11 70:5,8	<b>13cv31881</b> 2:10		162:24 163:5
136:11 162:3,3	115:21,25	<b>13cv32627</b> 2:11	<b>19034</b> 4:12	
171:19 179:21	117:19 120:4	102:1,1 122:15	<b>191</b> 5:22	
211:5 246:22	120:17 121:6	122:18,19	<b>192</b> 5:23	
250:20 252:19	121:10,25	<b>145:18</b> 6:5	<b>196</b> 5:24	
255:3	122:21 134:8	192:7 247:3,14	<b>1987</b> 51:5	
<b>youve</b> 7:13	145:20 154:4,7	250:11,23	<b>199</b> 6:4	
12:22,25 14:16	154:13,14,17	253:21	<b>1990s</b> 63:3 95:18	
17:6,21 19:24	177:20 218:6	<b>1400</b> 4:15	97:1	
20:15 21:8	222:25	<b>114th</b> 84:5	<b>14cv09195</b> 2:12	
26:8 27:4	<b>000plus</b> 145:24	<b>115</b> 5:16	<b>14cv09517</b> 2:13	
34:22 40:21	<b>02</b> 5:16	<b>116</b> 5:17	<b>14cv10640</b> 2:14	
41:4 43:17	<b>03</b> 5:17	<b>119</b> 5:18	<b>14cv12756</b> 2:15	
53:15 54:24	<b>05</b> 5:18	<b>11year</b> 251:12	<b>14cv13023</b> 2:16	
56:5,20 60:9	<b>050396</b> 105:22	<b>251:18,25</b>	<b>1499</b> 17:13	
60:10,17 78:1	<b>09</b> 5:19	<b>12</b> 5:16,24 17:11	<b>14cv14664</b> 2:17	
87:2,5 88:25	<b>1</b>	252:23 253:10	28:19 30:4	
89:4,9 91:8	<b>1</b> 5:2,13,17,19	<b>14cv16061</b> 2:18	254:19	
		<b>12</b> 5:16,24 17:11	<b>14cv19110</b> 2:19	
		56:11,13 137:7	<b>14cv22079</b> 2:20	
		196:7 197:21	<b>14cv24911</b> 2:21	
		<b>120</b> 5:19,20	<b>14cv24999</b> 2:22	
		<b>122</b> 5:21	<b>14cv28620</b> 2:23	
			<b>2</b>	
			<b>2</b> 1:3,7,8,9,10,11	
			1:12,13,14,15	

Michael P. Woods, M.D.

Page 300

1:16,17,18,19	87:10,11,16	<b>29</b> 137:7	<b>48</b> 5:13 102:1	238:3,7
1:20 2:2,3,4,5	161:5	<b>3</b>	<b>5</b>	<b>70</b> 140:9
2:6,7,8,9,10,11	<b>201</b> 6:5	<b>3</b> 5:15,17,18	<b>5</b> 1:22 3:2,12 5:3	<b>700</b> 154:4,7,14
2:12,13,14,15	<b>2010</b> 118:22	102:20,21	5:17 7:1 48:16	154:17
2:16,17,18,19	121:10,22,25	116:12 125:1	49:14 116:3,4	<b>7011100</b> 4:6
2:20,21,22,23	122:11,15,17	144:4,8,18	116:8,9 117:9	<b>70s</b> 204:12
2:24 5:14,19	122:19 124:10	145:11,12	125:1 189:8	<b>75</b> 18:12 122:21
6:1 16:12	225:13,20	146:8,10,13	199:3 215:5	194:8 209:1
17:16,21 65:1	<b>2011</b> 90:1 122:5	148:19 162:18	237:20 244:6	<b>76</b> 223:11
65:2 70:5,8	225:20,23	190:25 197:24	<b>50</b> 115:21,25	<b>772</b> 228:2
144:8 145:12	<b>2012</b> 89:13	200:11 207:5	<b>8</b>	<b>8</b> 5:20,20 120:21
145:20,24	167:9,12	224:18 225:9,9	140:4 170:15	120:22 176:1,3
146:10,13	217:14 225:17	<b>30</b> 121:6,10	207:5	200:13
148:19 174:11	<b>2013</b> 57:3,8,11	257:13	<b>500</b> 4:11 16:13	<b>80</b> 140:9 141:20
174:11 177:20	57:13,18 58:5	<b>300</b> 4:5	17:22 218:6	205:24 231:17
207:6 218:6	58:11 60:14,25	<b>31</b> 137:7 162:23	<b>510</b> 182:1,3,17	233:7
222:25 238:4,6	82:22 119:17	<b>31st</b> 225:17	<b>5131701</b> 4:12	<b>80s</b> 141:15
<b>20</b> 55:1 174:11	120:9	<b>32</b> 162:25	<b>5131885</b> 4:12	204:10 205:15
259:15	<b>2014</b> 57:4,16,20	<b>33</b> 120:17	<b>522</b> 43:1,5,6,10	<b>816</b> 4:6,6
<b>200</b> 154:13	58:1,7,11,16	174:11 222:19	43:12 44:2,4,9	<b>82</b> 223:12
<b>2000</b> 58:2	60:1	<b>3377</b> 1:24	45:6	<b>84</b> 238:3
<b>2000s</b> 63:3 95:15	<b>2015</b> 1:22 3:2,12	<b>34</b> 102:1 163:3	<b>5312372</b> 4:6	<b>85</b> 139:5
97:1	97:1	254:6 66:22	<b>550</b> 55:6	<b>86</b> 238:4
<b>2001</b> 59:23	82:15 192:11	223:22	<b>56</b> 190:12	<b>877</b> 1:24
<b>2002</b> 60:5 115:5	193:18 256:21	<b>36</b> 222:19	<b>5672</b> 1:24	<b>88</b> 51:5
115:19 116:11	<b>20plus</b> 76:8	<b>370</b> 1:24	<b>58</b> 217:19	<b>89</b> 201:22
116:14,22	<b>21</b> 180:7 255:16	<b>39</b> 203:11,13,17	<b>591</b> 1:24	223:10
119:14 120:7	<b>212</b> 199:16	205:3,14 225:9	<b>6</b>	
124:18 125:1	<b>22</b> 163:1	248:18 254:5	<b>6</b> 5:18 119:20,21	<b>9</b>
154:12,12	<b>223</b> 6:7	<b>39157</b> 4:16	161:11 199:1	<b>9</b> 3:12 5:21
<b>2003</b> 59:23	<b>227</b> 6:9	<b>3i</b> 199:15	200:11 223:12	122:7,8 161:16
<b>2004</b> 58:1 60:1,7	<b>23</b> 5:21 122:15	<b>4</b>	228:9	176:4 199:1
115:6 117:22	<b>2327</b> 1:4	<b>45:3,16</b> 9:15	<b>601</b> 4:16,16	223:10 225:12
119:12	<b>236</b> 6:11	55:11 115:12	<b>61</b> 217:14	<b>90</b> 202:2 205:25
<b>2006</b> 154:14,15	<b>23rd</b> 225:13	115:13 116:8	<b>64112</b> 4:6	<b>90s</b> 140:5,7
<b>2007</b> 16:19,21	<b>246</b> 5:9	116:10,11,14	<b>65</b> 5:14	141:15 204:10
16:22 17:9	<b>25</b> 117:19 163:4	199:2,3 201:23	<b>650</b> 55:9	205:16
19:13 22:3	<b>253</b> 5:10	224:4,5 255:16	<b>6th</b> 256:21	<b>91</b> 201:23 238:7
23:1,25 82:3	<b>256</b> 5:4	<b>40</b> 3:12 66:22	<b>917</b> 1:24	
111:23 112:1	<b>257</b> 5:5	<b>400</b> 4:11 33:15	<b>93</b> 201:23	
112:16 162:17	<b>25th</b> 53:14,15,19	134:8	<b>94</b> 238:6,11	
165:19 213:25	54:14,17,25	<b>44</b> 225:9	<b>942</b> 217:13	
214:3 254:19	<b>26</b> 5:14 48:6	<b>440</b> 190:12	<b>9485711</b> 4:16	
<b>2008</b> 16:22	<b>267</b> 4:12,12	<b>4740</b> 4:5	<b>95</b> 141:11	
110:12 254:23	<b>26year</b> 221:25	222:6		
<b>2009</b> 8:25 82:4				

Michael P. Woods, M.D.

Page 301

237:12,16  
238:1  
**96** 141:12  
**9854500** 4:16